SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
DOCUMENT BINDER INDEX

June 18, 2013

"Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism"

Exhibit Number	Document
1	June 14, 2013 Majority Memorandum
2	June 17, 2013 Scientific American Article, by Dina Fine Maron, "U.S. Bioterror Detection Program Comes Under Scrutiny"
3	Appendix C: Glossary
4	Glossary of Acronyms
5	Table of Biological Threat Agents
6	June 7, 2103 Congressional Research Service Memorandum: Information for a hearing on the Department on the Homeland Security BioWatch program
7	July 8, 2012 Los Angeles Times Article, by David Willman, "The biodefender that cries wolf"
8	October 22, 2012 Los Angeles Times Article, by David Willman, "BioWatch technology couldn't detect lethal germs, tests found"
9	December 21, 2012 Los Angeles Times Article, by David Willman, "Troubled BioWatch program at a crossroads"
10	June 16, 2013 Los Angeles Times Article, by David Willman, BioWatch faces congressional hearing this week"
11	July 19, 2012 Letter to Centers for Disease Control Prevention Director Thomas Frieden
12	November 16, 2012 Response to our July 19, 2012 Letter to Centers for Disease Control and Prevention Director Thomas Frieden
13	July 19, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
14	November 13, 2012 Letter to Centers for Disease Control Prevention Director Thomas Frieden
15	January 25, 2012 Response to our November 13, 2012 Letter to Centers for Disease Control and Prevention Director Thomas Frieden
16	November 13, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
17	January 25, 2012 Response to our November 13, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
18	January 31, 2013 Letter to Department of Health and Human Services Secretary Kathleen Sebelius
19	June 10, 2013 Email From: DHS; To: Committee Staff; Subject: Number of BARS
20	June 14, 2013 Email From: DHS; To: Committee Staff; Subject: Jurisdictions

Exhibit Number	Document
21	October 9, 2012 Email From: Jasmine Chaitran, CDC; To: Toby Merlin; Subject: Total Number of BARS since BioWatch inception
22	May 29, 2013 Email From: Shana Bevin, CDC; To: Committee Staff; Subject: Breakdown of the number of BARS
23	August 13, 2011 Email From: Segaran Pillai (DHS); To: Toby Merlin; Subject: Signatures on Current PHAA Document
24	December 8, 2011 Email From: Robert Hooks; To: Michael Walter (DHS); Subject: Update on Program
25	[redacted]
26	January 3, 2012 Email From: Cristin Willner (CTR); To: Segaran Pillai (DHS); Subject: BioWatch Read Ahead Material, attachment of background included
27	April 23, 2012 Email From: Douglas Drabkowski (DHS); To: Segaran Pillai (DHS); Subject: TEMP from OHA
28	June 14, 2012 Science & Technology Directorate Chem-Bio Division Review and Comment BioWatch Documents-"Acquisition Program Baseline (APB) for BioWatch Gen-3 Autonomous Detection System"
29	July 12, 2012 Email From: Wendy Hall; To: Douglas Drabkowski and Segaran Pillai; Subject: Gen-3 IRT Outbrief
30	June 19, 2012 Email From: Tara O'Toole; To: Brian DeVallance; Subject: Bio Meeting
31	June 25, 2012 Email From: Erin O'Connor; To: Tara O'Toole; Subject: BioWatch IRB
32	August 6, 2012 Email From: Douglas Drabkowski; To: Segaran Pillai; Subject: BioWatch Gen-2 Data
33	September 7, 2012 DHS Acquisition Decision Memorandum, Subject: BioWatch Generation-3 Acquisition; From: Doctor Alexander Garza, Assistant Secretary for Health Affairs; To: Rafael Borras, Under Secretary for Management
34	May 22, 2011 Email From: Toby Merlin (CDC); To: Beth Bell (CDC) and Thomas Hearn (CDC); Subject: OPR on LRN-Draft Outline of Presentation
35	May 26, 2011 Email From: Michael Farrell; To: Toby Merlin (CDC); Subject: Private Conversation with Mike Walter and Ulana Bodnar and email chain
36	June 24, 2011 Email From: Toby Merlin (CDC); To: Michael Farrell, Richard Kellogg, Harvey Holmes; Subject: Incident Notice-BioWatch Notification-F. Tularensis, Houston, TX CLOSED
37	June 9, 2011 Email From: Toby Merlin (CDC); To: Richard Kellogg (CDC); Subject: LRN Comment on Proposed Email to Ranhofer about BioWatch Gen-3 Signature Concern
38	August 10, 2011 Email From: Harvey T. Holmes; To: Toby Merlin (CDC); Subject: Multiplex
39	September 9, 2011 Email From: Richard Kellogg; To: Dan Sosin, Joanne

Exhibit Number	Document
	Andreadis, Toby Merlin (all CDC); Subject: Feedback on Tara O'Toole Discussion
40	September 9, 2011 Email From: Toby Merlin (CDC); To: Dan Sosin (CDC); Subject: Feedback on Tara O'Toole Discussion
41	October 13, 2011 Email From: Toby Merlin (CDC); To: Segaran Pillai (DHS); Subject: Signatures on Current PHAA Document
42	October 19, 2011 Email From: James Hayslett (CDC); To: Toby Merlin (CDC); Subject: Conflict Between OHA and S&T
43	November 17, 2011 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Follow-Up from Toby Merlin to NYC DOH
44	November 17, 2011 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Letter We/DPEI are Sending to DHS-OHA About Our Concerns on Gen-3 ORD
45	November 17, 2011 Email From: Beth Maldin (Health.NYC.Gov); To: Toby Merlin (CDC), Colin Stimmler, Issac Weisfuse (CDC) and Stephen Papagiotas (CDC); Subject: Draft DHS OT&E Guidance
46	May 6, 2012 Email From: Toby Merlin (CDC); To: Beth Bell (CDC); Subject: Follow-Up on NYC BioWatch Concerns
47	May 16, 2012 Email From: Toby Merlin (CDC); To: Jasmine Chaitram (CDC); Subject: Question to Follow-Up BioWatch Indoor Working Group
48	May 23, 2012 Email From: Toby Merlin (CDC); To: Beth Bell (CDC) and Tracee Treadwell (CDC); Subject: Thoughts for 11:30 Call about Beth's Upcoming Meeting with Tara O'Toole
49	June 20, 2012 Email From: Beth Bell (CDC); To: Ali S. Khan (CDC); Subject: BioWatch Story
50	June 21, 2012 Email From: Ali S. Khan (CDC); To: Beth Bell (CDC); Subject: BioWatch Story
51	June 29, 2012 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Life, Liberty and the Pursuit of Assays
52	July 25, 2012 Email From: Toby Merlin (CDC); To: Stephen A. Morse (CDC); Subject: Garza's Statement
53	July 26, 2012 Email From: Stephen A. Morse (CDC); To: Toby Merlin (CDC); Subject: Gen-3
54	July 26, 2012 Email From: Angela Webber (CDC); To: Toby Merlin (CDC) and Stephen A. Morse (CDC); Subject: Congressional Letter and Mention of "Trace" Detection
55	August 16, 2012 Email From: Angela Webber (CDC); To: Stephen A. Morse (CDC); Subject: Trace Amounts
56	October 22, 2012 Email From: Michael Farrell (CDC); To: Toby Merlin (CDC); Subject: Question #3 About the LOD Summaries
57	July 9, 2012 Letter; From: Bennie G. Thompson; To: Secretary Janet Napolitano; Subject: LA Times Article on BioWatch Gen-3 Technology

Document 1

THE COMMITTEE ON ENERGY AND COMMERCE

Memorandum

June 14, 2013

TO: Members, Subcommittee on Oversight and Investigations

FROM: Majority Committee Staff

RE: Hearing on BioWatch and Public Health Surveillance

On Tuesday, June 18, 2013, at 10:00 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism." This hearing is an examination of the effectiveness and efficiency of BioWatch, a Department of Homeland Security (DHS) program, and its relationship with the Centers for Disease Control and Prevention (CDC) and state and local public health authorities.

I. WITNESSES

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

Toby L. Merlin, M.D.
Director
Division of Preparedness & Emerging Infections
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

II. BACKGROUND

The BioWatch program was started in 2003, and is managed by the DHS Office of Health Affairs. BioWatch is an early warning system for detection of a large-scale, bioterrorist attack using pathogens that have been covertly released into the air.

BioWatch deploys collectors in 34 of the largest U.S. metropolitan areas in outdoor locations to detect the possible aerosol release of a bioterrorism pathogen. This program also includes three indoor deployments and special event capacity. By detecting a biological attack much earlier than through public health surveillance, BioWatch could save more lives because medications would be distributed to the population before many exposed individuals became ill. BioWatch uses polymerase chain reaction (PCR) laboratory testing designed to detect an

aerosolized biological attack from several specific biological agents considered high-risk for use as biological weapons, such as anthrax. BioWatch has three main elements coordinated by different agencies: sampling, analysis, and response. The sampling component involves collectors with filters collecting air samples. These filters are manually collected, usually at 24-hour intervals. The CDC coordinates analysis, and the laboratory testing of the samples, though the testing is carried out in state and local public health laboratories. Local jurisdictions are responsible for the public health response to positive findings.

The detection of biological agent DNA by the BioWatch program is referred to as a BioWatch Actionable Result (BAR). A BAR is defined as one or more PCR-verified positive result(s) from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents. If there are positive findings, federal, state, and local officials review findings from other collectors, conduct additional tests on samples, and review additional relevant information. If it is determined that an actual attack has occurred, several public safety and health measures take place, including potential mass prophylaxis of exposed populations and requesting vaccines or anti-viral medications from the Strategic National Stockpile.

Under the current BioWatch system called Generation 2 (Gen-2), the detection process can take 12 to36 hours and entails labor costs for manual collection and analysis. Because prompt treatment may minimize casualties in a bioterrorism event, federal efforts have aimed to reduce the inherent delay in daily BioWatch filter collection by developing autonomous detection systems. Unlike the current BioWatch system, these autonomous systems would not only collect the samples, also identify the specific agent.

Since 2004, DHS has been pursuing a technology – which is to be the third generation of deployed BioWatch technology, called BioWatch Generation-3 (Gen-3). The goal of Gen-3 is to improve upon existing technology by enabling autonomous collection and analysis of air samples using the same laboratory science that is carried out in manual processes in the current system. The new technology would operate as a self-contained "laboratory-in-a-box" that would reduce the time to six hours between potential exposure and confirmation of the presence of biological pathogens and eliminate manual collection and analysis costs. In addition to this technological enhancement, DHS has aimed to widen deployment of the Gen-3 collectors to more cities, and to add collectors to each of these cities to widen population coverage for each area.

BioWatch currently costs about $85 million a year to operate, with over $1 billion spent since 2003. However, an internal DHS document from December 2011 projected the anticipated future cost for operating Generation 3 at $7.7 billion for 15 years. According to the Government Accountability Office (GAO), the cost of Gen-3 without risk adjustments is estimated to be about $5.8 billion over 10 years. These cost estimates were based on technologies that failed to meeting operational requirements in testing. There is no current cost estimate for Gen-3 because the BioWatch program is completing an Analysis of Alternatives (AoA), and will update the cost estimate to reflect any changes in the program.

Acquisition Status

The BioWatch Gen-3 acquisition process has had difficulties maintaining target costs goals and meeting technical requirements. The estimated lifecycle costs of the Gen-3 program

increased between 2009 and 2011 from $2.1 billion to $5.8 billion. The GAO questioned the prior cost estimates and concluded that they "did not account for risk and uncertainty, and it was not based on the work breakdown structure for Gen-3 and as such, DHS did not have assurance that it captured all relevant costs."[1]

The competing technologies for Gen-3 have also failed to meet requirements, leading DHS and the Congress to put Gen-3 on pause.

Last September, Congress cut approximately $40 million that DHS had requested for Gen-3. Congress in effect also required the Secretary of DHS to certify that the science of Gen-3 is proven before procurement can be permitted. During the passage of the Consolidated and Further Continuing Appropriations Act of 2013[2] (the CR), the House and Senate appropriators issued the following explanatory statement that instructs DHS with respect to the Gen-3 program:

> The Committees have consistently demonstrated strong support for the development of an early warning network to detect biological agents to speed response and recovery from a terrorist attack. While the Committees support OHA's ongoing efforts to improve the Nation's biological detection capabilities, serious concerns have been raised about the Biowatch Generation 3 program, to include scientific validity and delays in execution that have created large carryover balances. The Department is encouraged to continue with Phase II, Stage I activities, as currently planned with available carryover funding, to ensure candidate systems meet entry criteria through performance testing. However, prior to entering Phase II, Stage 2 that includes down-selection for a single solution and entering operational testing and evaluation, the Secretary shall certify to the Committees that the science used to develop the technology is proven and warrants operational testing and evaluation.

It is unclear what will be required to show that the science is proven. At a minimum, the acquisition process will impose certain requirements before Gen-3 can be certified. In September 2012, DHS revised its acquisition strategy and ordered an AoA, and re-evaluated the mission and goals of Gen-3. The AoA must include a Cost-Benefit Analysis of the deployed Bio-Watch Gen-2 performance versus the proposed Gen-3 performance. The AoA is underway and is expected to conclude in the fall of 2013.

In addition, other studies and information-gathering efforts may further delay possible certification of Gen-3. Recently, Dr. Walter, the DHS BioWatch program manager, asked the National Academies of Science (NAS) to convene an ad hoc committee to conduct a study and prepare a report that will evaluate and provide guidance on appropriate standards for the validation and verification of PCR tests and assays used by the BioWatch program. The efforts are expected to make adequate performance data available to public health and other key decision makers so that they have a sufficient confidence level to facilitate the public health response to a BAR. The requested report is not expected to be issued until the latter part of 2014. In addition, DHS is also funding a June 25-26, 2013, NAS workshop to explore alternative biodetection systems to Gen-3.

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[1] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 30.
[2] Explanatory Statement of Managers associated with Public Law 113-6, March 26, 2013.

Committee investigation

On July 19, 2012, Chairman Upton and O&I Subcommittee Chairman Stearns opened an investigation into the BioWatch program, to examine its performance and its impact on the nation's public health system. Request letters were sent to both DHS and CDC. The investigation followed up on a July 8, 2012, *Los Angeles Times* article, which reported that BioWatch had been plagued by false alarms and other failures. In addition, state and local health officials reportedly expressed their lack of confidence in BioWatch.

DHS disputed the *Los Angeles Times* article. On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

On November 13, 2012, Chairman Upton and Subcommittee Chairman Stearns sent request letters to DHS and CDC concerning the BioWatch program. The Committee was following up on an October 23, 2012 *Los Angeles Times* article, which reported that a BioWatch system was operating with defective components. In addition, the requests were reaffirmed and expanded because of inadequate responses to the July 12, 2012, request letters.

On January 31, 2013, Chairman Upton and O&I Subcommittee Chairman Murphy sent a request letter to HHS Secretary Kathleen Sebelius reaffirming the November 13, 2012, document request sent to CDC and asking that the document production be expedited.

Both DHS and CDC have provided documents. Committee staff has also conducted interviews with officials from DHS and CDC.

III. ISSUES

Do state and local authorities in BioWatch jurisdictions have adequate guidance from DHS on what response actions to take following a BioWatch Actionable Result?

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?

What factors led to the delays in the Gen-3 acquisition timeline?

What improvements have been made to Gen-2, the current BioWatch program technology?

What additional type of information will CDC look for before taking public health actions with the distribution and dispensing of medical counter-measures?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin or Carl Anderson at (202) 225-2927.

Document 2

SCIENTIFIC AMERICAN™

Permanent Address: http://www.scientificamerican.com/article.cfm?id=us-bioterror-detection

U.S. Bioterror Detection Program Comes Under Scrutiny

A national air sampling system tasked with picking up terrorist biological attacks faces scrutiny

By Dina Fine Maron | Monday, June 17, 2013 | 2 comments

A cutting-edge biological terror alert system detected a potential threat in the air one morning back in 2008, threatening to derail then-Sen. Barack Obama's acceptance speech in Denver for his party's presidential nomination at the Democratic National Convention. Initial results from a pricey national air sampling system suggested that bacteria that could cause tularemia had been detected. The microbe, *Francisella tularensis*, might have been weaponized to cause the infectious disease.

Pin it

Francisella tularensis.
Image: Missouri Department of Health and Senior Services

Public health officials sprang into action and tested further samples from the area that triggered the system, but turned up negative results. The alert, like others issued by the system in the past decade, was ruled to be a false alarm. Obama still made his acceptance speech that night, of course, in an open-air stadium as planned. But the system's critics say BioWatch has repeatedly triggered an alarm when no threat has existed. Now the program faces the scrutiny of Congress.

BioWatch, an alert system designed to be an early detection system for airborne threats such as anthrax and smallpox, was unveiled in 2003 by Pres. George W. Bush. In his State of the Union address, he talked about the system, saying he was, "deploying the nation's first early warning network of sensors to detect biological attack." Since then the system has cost $1 billion and been met with mixed reviews. A committee convened by the Institute of Medicine (IOM) and the National Research Council (NRC) said in a 2011 report no expansion of the program should be made without better collaboration with the existing public health system. The panel also called for further analysis of the program and how it could be used to reduce mortality and morbidity.

The network of outdoor and select indoor air samplers was installed, under the aegis of the U.S. Department of Homeland Security (DHS), in more than 30 U.S. metropolitan areas to sniff the air for potential threats. The filters from those aerosol collectors are retrieved for analysis in state or county public health laboratories.

Whereas technically the potential threats detected by the system in the past were not false positives—they did accurately pick up tiny, background amounts of DNA from organisms naturally present in the environment— in effect, they were false alarms because they signaled the potential occurrence of a terrorist attack when none had occurred. Some public health officials have said they are hesitant to rely on the program. Others say it is an important piece of the bioterror response puzzle.

"The way I look at BioWatch is that it is a tool," says Umair A. Shah, executive director of the Harris County Public Health and Environmental Services Department in Texas. "It is one of many tools that are available to public health decision—makers and needs to be kept in the context of that paradigm. The sum of all those tools is really how we go about making sound public health decisions." Sensors in area around Houston and Harris County had the first-ever positive result through BioWatch in 2003. Like the later DNC incident, BioWatch picked up indications of *F. tularensis*. Those readings also turned out to be a false alarm; BioWatch again had detected organisms naturally present in the environment.

The value of the system, even with its false alarms, is that it could give public health officials the first clues of a bioterror attack. "You don't necessarily want to make [BioWatch] less sensitive to avoid false positives," says Seth Foldy, a physician who works on public health informatics and served on the NRC—IOM panel looking at the program. The tricky part, he says, is finding a way to make the system sensitive enough so that it would pick up actual disease-causing agents in the event of a bioterror threat, but specific enough to be able to distinguish them from very closely related bacteria that may exist in the environment but do not lead to human disease.

A House subcommittee is set to examine the program Tuesday, with representatives from the DHS and the U.S. Centers for Disease Control set to discuss the system's future. "The BioWatch Program is the only federally—managed, locally—operated nationwide bio—surveillance system designed to detect select aerosolized biological agents," says DHS spokesman SY Lee. "BioWatch provides public health officials with a warning of a biological agent release, before potentially exposed individuals develop symptoms of illness."

Against the backdrop of lukewarm reviews, however, a planned expansion of BioWatch, Generation 2.5, was canceled in fall 2008. The next proposed stage of the system, Generation 3, will be under discussion at the hearing. The system as it stands now is designed so that the time between sample collection and laboratory results indicating potential biological aerosol release is between 10 to 36 hours. With future iterations of the program the hope is to get initial analysis of the samples wrapped up within six hours. For Generation 3, DHS is looking into including autonomous biodetection technology to help eliminate the need for manual filter retrieval and analysis. Still, confirmatory tests would still be required raising questions about how much time would be saved and if it would result in faster response times and disbursement of emergency drugs that could help avoid human sickness or death.

At the very least it may help preliminary results get out faster. "The difference it would make," says Bob England, director of the Maricopa County Department of Public Health, which covers the Phoenix metropolitan area, "is you would get your first inkling that something might be going on hours earlier. That would give you that much more time to get people together and ready to evaluate the confirmatory results when they do come back so it does make the response earlier."

In the current fiscal environment there is also concern from some public health offices that dollars allocated to detecting biological threats through BioWatch may be competing with the ones needed to provide complementary information to help detect threats—such as picking up any uptick in certain symptoms at hospitals through robust health surveillance. According to National Association of County and City Health Officials (NACCHO), 59 percent of local health departments rely exclusively on federal funding to support their emergency preparedness programs. As cuts have been made to public health emergency response in recent years, says Jack Herrmann, senior advisor and chief of public health preparedness at NACCHO, that makes it more difficult to conduct consistent public health monitoring and create optimal response plans.

Document 3

Appendix C: Glossary

Acquisition Decision Authority: The individual designated in accordance with criteria established by the Department Chief Acquisition Officer to approve entry of an acquisition program into the next phase of the acquisition process. Formerly known as a Milestone Decision Authority (MDA).

Acquisition Decision Event: A predetermined point within the acquisition phases at which the investment will undergo a review prior to commencement of the next phase. Formerly known as a Key Decision Point (KDP).

Agent Data: Data containing sample analysis or results.

BioWatch Actionable Result (BAR): One or more PCR-verified positive results from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents (i.e., three of three signatures). If PCR-verified positive results are obtained for two BioWatch agents on a single collector, this is considered one BAR. See below for PCR-verified definition.

BioWatch Autonomous detector: The BioWatch Autonomous Detector is a networked device capable of achieving the following: (1) Rapidly process and accurately analyze aerosol samples with a high level of confidence (2) Automate and integrate the major system functions into the detector including aerosol sample collection, preparation, analysis, and analytical results reporting (3) Operate in its intended outdoor and indoor environments (4) Disseminate and archive analysis results and system operational data.

BioWatch Collector: Collector is the generic term used to describe the devices used to extract particulate matter from the air and deposit it onto a filter that is subsequently analyzed at a laboratory.

BioWatch Jurisdiction: For purposes of this document, the term "BioWatch Jurisdiction" will be used to describe each of the BioWatch program metropolitan areas. BioWatch is operational in more than 30 of the largest metropolitan areas in the United States. These areas may be composed of one or more city, county, state, and/or regional BioWatch Jurisdictions or decision making bodies. Officials in each BioWatch Jurisdiction should interpret this term to reflect their unique decision-making and communications structure.

BioWatch Signal: A BioWatch Signal is defined to mean detector analysis results that exceed specified thresholds. This enables a means of filtering high frequency data to assure that results that may contain significant content are automatically brought to the user's attention.

Data centers: High-availability Information Technology facilities where G3BOSS is hosted. These data centers provide data processing, backup, storage, and dissemination of information in a secure environment.

DNA signature: A region of a DNA sequence that is specific to a certain organism or genus.

Function Cycle: A function cycle refers to each function's (sub-system) unique cycle of operation thus requiring a level of detail that includes independent monitoring/reporting for each function.

Gen-3 BioWatch Operations Support System (G3BOSS): The Gen-3 BioWatch Operational Support System consists of the information and data management technology required to deliver high-availability data services to the Gen-3 user.

Jamming: Emitting a signal from a communications device that creates constant or partial blockage of an established telecommunications channel, e.g. Creating collisions on a wired network to interrupt normal data communication; generating random radio signals on a known frequency to disrupt normal data transmission on that frequency.

Key Performance Parameter (KPP): Those attributes or characteristics of a system/program/project that are considered critical or essential parts of an effective system/program/project capability.

[redacted] The average biological agent air concentration over the collection period, assuming a probability of detection equal to or greater than 98%. The average air concentration of agents over the collection period includes flow rate, collection efficiency, collection duration, and limit of detection (LOD) of the analysis subsystem. For example, if the LOD of the analysis subsystem is 900 organisms, the collection duration is 3 hours, the collection efficiency is 90%, and the flow rate is 100 liters per minutes, the system-level sensitivity of the detector is 56 organisms per cubic meters.

System [redacted] System specificity is defined as the ability of the Gen-3 BioWatch System to detect strains of the target species without detecting near-neighbors or background organisms.

Time to Detect: The elapsed time between intake of the agent and generation and transmission of the analytical results.

Document 4

Glossary of Acronyms

BAR	A BioWatch actionable result (BAR) is defined as one or more PCR-verified positive results from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents (i.e. three of three signatures). If PCR-verified positive results are obtained for two BioWatch agents on a single collector, this is considered one BAR. See below for PCR-verified definition.
BioWatch Collector	Collector is the generic term used to describe the devices used to extract particulate matter from the air and deposit it onto a filter that is subsequently analyzed at a laboratory.
BRRAT Laboratory	Bioterrorism Rapid Response and Advanced Technology Laboratory. This is the primary bioterrorism laboratory located at the CDC. It is a state-of-the-art facility that develops and validates new Laboratory Response Networks (LRN) assays, processes suspicious samples, and provides 24-hour diagnostic support to bioterrorism response teams.
BTRA	Bioterrorism Risk Assessment. This is an evaluation conducted by The Department of Homeland Security Science and Technology Directorate every two years and it began in 2006. It provides a mechanism for assessments and reprioritization of federal capabilities in response to changing adversary capabilities.
ConOps	Concept of Operations. A term used to describe the characteristics of a proposed system from the viewpoint of an individual who will use that system. It is used to communicate the quantitative and qualitative system characteristics to all stakeholders. It may include the goals and objectives of the system, strategies, tactics, policies, and constraints, specific operational processes for fielding the system and processes for initiating, developing, maintaining, and retiring a system.
Ct	Cycle threshold. A term used in real-time PCR describing the cycle number at which fluorescence intensity exceeds threshold baseline.
LRN	Laboratory Response Network of the Department of Health and Human Services, Centers for Disease Control and Prevention. The LRN maintains a

	national and international network of laboratories fully equipped to respond to acts of biological or chemical terrorism, emerging infectious disease, or other public health threats and emergencies.
ORD	Operational Requirements Document. This document describes what intended role the system will be used for and therefore determines what requirements the system must have.
PCR	Polymerase chain reaction is a laboratory technique used to amplify a DNA fragment present in BioWatch samples as part of the process of detecting genetic fingerprints of intentionally released aerosolized biological agents.
PCR-verified positive test	First event that triggers an initial BioWatch response. A PCR-verified positive result is defined as a result that meets a particular threshold and algorithm (i.e. three of three signatures are reactive) for a specific BioWatch agent. When a sample is deemed reactive during the screening assay (one agent signature crosses the threshold), a verification panel for that particular agent is tested.
PSU	Portable Sampling Unit (PSU) is a type of sample collector. The PSU is designed for use as a constant flow air sampler. It is used to pull air through a filter for the collection of airborne pathogens for analysis. A unique feature of the PSU sampling system is that the sample inlet is adjustable between 48 and 72 inches above the ground. The PSU has been custom designed to enclose and provide chain of custody for the pump, flow controller, flow meter, filter holder, and all electronics inside two individual, lockable, weather-resistant boxes.
SNS	Strategic National Stockpile. This is the national repository of antibiotics, vaccines, chemical antidotes, antitoxins and other critical medical equipment and supplies. In the event of a national emergency involving bioterrorism or a natural pandemic, the SNS has the capability to supplement and re-supply local health authorities that may be overwhelmed by the crisis, whit response time as little as 12 hours. The SNS is managed by the Centers for Disease Control and Prevention with support from other agencies in the Department of Health and Human Services and the U.S. Government.

Document 5

Table of Biological Threat Agents

Common Name	Species & Sub-Species	Description
Anthrax	*Bacillus anthracis*	Anthrax is an infectious disease caused by *B. anthracis* spores that are ingested by grazing animals.[1] Humans are infected through inhalation of spores or ingestion of infected animals. Anthrax leads to skin infection, respiratory infection, and gastrointestinal infection. Inhalation of anthrax is fatal (90% of identified cases led to death). Skin infection and gastrointestinal infection may be treated with antibiotics, unless the infection leads to the bloodstream resulting in death.
Brucellosis Malta Fever Undulant Fever Mediterranean Fever Rock Fever Gibraltar Fever	*Brucella melitensis* *Brucella suis* *Brucella abortus* *Brucella canis* *Brucella pinnipediae* *Brucella cetaceae*	Brucellosis is a disease that infects cattle, goats, camels, pigs, and dogs.[2] Humans contract the disease from eating infected food products. Infection is rare in the U.S., roughly 100-200 cases per year. Symptoms include on/off fever persisting for months, headaches, muscle/back pain, swelling of heart, and fatigue. Mortality rate is low (<2%) with appropriate treatment of antibiotics.
Plague Bubonic Pharyngeal Meningeal Septicemic Pneumonic	*Yersinia pestis*	Plague is a deadly infectious disease, popularized as the bubonic plague from the Middle Ages.[3] The three most common forms of plague are Bubonic, Pneumonic, and Septicemic. Human contraction comes from flea bites or inhalation of bacteria. Fleas contract the disease from rabbits, squirrels, prairie dogs, and cats. Symptoms typically occur after 2-5 days of bacterial exposure. Mortality rate is high if treatment is not received in 24-hours after symptoms appear. Without treatment 50% of bubonic plague patients die and nearly all pneumonic plague patients die. Treatment can only reduce mortality rate to 50%.
Q Fever	*Coxiella burnetii*	Q Fever is a global infectious disease that infects sheep, goats, cattle, dogs, cats, birds, rodents, and ticks.[4] Humans contract the disease by inhaling or ingesting milk, urine particles, and fecal particles of infected animals. Humans can be infected by a single bacterium. Treatment with antibiotics is very effective leading to low mortality rates.
Tularemia Deerfly Fever Rabbit Fever Ohara Disease Lemming Fever Pahvant Valley Plague	*Francisella tularensis tularensis* (Type A) *Francisella tularensis holartica* (Type B) *Francisella novicida* *Francisella philomiragia*	Tularemia is an infectious disease caused by the species *Francisella.* The bacterium is carried by small rodents (rabbits, beavers, muskrats, rats, squirrels, raccoons, and skunks.).[5, 6] Ticks, flies, and mosquitoes spread the disease to humans through bites. Tularemia can easily be aerosolized and spread as a bioterror agent. Treatment of Tularemia is very effective with antibiotics. Mortality rate is ~5% in untreated cases.
Smallpox	Variola major (Virus) Variola minor (Virus)	Smallpox is a deadly virus that has been eradicated by the WHO in the 1970s.[7] Variola major causes life threatening symptoms to those not vaccinated with the smallpox vaccine. Variola minor causes a mild infection that rarely leads to death. Contraction of Smallpox without vaccination has a mortality rate of nearly 30%. The virus is contracted through human-to-human contact and contact with contaminated objects. The virus can be aerosolized and distributed easily as a bioterror agent.

Viral Encephalitis	Poliovirus Echovirus Cytomegalovirus Adenovirus Measles/Rubella Epstein-Barr Virus Herpes Simplex Virus Varicella-Zoster Virus	Encephalitis can be caused by diverse viral infections. It ... a rare infection that is more susceptible in the first year of life or with the elderly.[8] Encephalitis is characterized as inflammation and irritation of the brain due to viral infections. Humans contract the virus through airborne infection, insect bites, and ingesting contaminated food. Symptoms lead to fever, vomiting, headache, light sensitivity, seizures, paralysis/body stiffness, coma, amnesia, rash, and pneumonia.
Viral Hemorrhagic Fever Lassa Fever Crimean-Congo Fever Hantavirus Fever Ebola Fever Marsburg Fever	Arenaviridae (Virus) Bunyaviridae (Virus) Filoviridae (Virus) Flaviviridae (Virus)	Viral Hemorrhagic Fevers are caused by a diverse array of viruses. Clinical symptoms range from mild to severe. The most popularly characterized VHF is the Ebola virus. Ebola is a deadly illness that affects humans and primates.[9] Mortality rate of Ebola is as high as 90%. There is no known treatment for Ebola. All the viruses are carried by small rodents and insects. Humans contract the virus via insect bites, ingesting contaminated food, and inhaling particles.
Botulism Botulinum Toxin (Types A-G)	*Clostridium botulinum*	*C. botulinum* is found globally in the soil and untreated water.[10] The bacterium produces hardy spores that create a neurotoxin. The toxin is highly infectious and in small dosages can cause severe poisoning. The toxin is noted for its ability to paralyze muscles. Around 110 cases of botulism occur in the U.S. yearly. A derivative of the neurotoxin is commonly used for Botox Therapy.
Staphylococcal Enterotoxin B (SEB)	*Staphylococcus aureus*	Staphylococcus bacteria thrive in unrefrigerated meats and dairy products.[11] The bacterium will excrete SEB toxins that lead to toxic shock syndrome. SEB is very stable and is easy to aerosolize. SEB inhalation leads to high levels of incapacitation and even death. *S. aureus* is a common source for food poisoning leading to diarrhea, nausea, intestinal cramping, fever, sore throat, chest pain, and vomiting.[12]
Melioidosis Whitmore's Disease	*Burkholderia pseudomallei*	Melioidosis is an infectious disease that affects humans and animals.[13] The bacteria causing the disease is predominately found in soil and contaminated water. The disease is global, but commonly found in the tropics. Human contraction comes from contamination of wounds, ingestion, and inhalation. [14] Incubation period may last from one day to many years. Symptoms can include ulcers, skin abscess, pulmonary infection, fever, headache, and septic shock. Animal species susceptible to Melioidosis are sheep, goats, swine, horses, cats, dogs, and cattle.[13] Treatment requires antibiotics from weeks to months. Mortality rate has been observed to be around 20-50%.[15]
Glanders	*Burkholderia mallei*	Glanders is a disease that affects horses, donkeys, and mules. It is mostly seen in parts of Asia, Africa, the Middle East, as well as Central and South America.[16] Humans can contract the disease via contact with infected animals. Glanders can easily be aerosolized and spread out. If inhaled can lead to severe disease. The bacteria can cause rashes, opening of wounds, fever, diarrhea, and lung abscesses. Treatment for Glanders is directed toward antibiotics, as there is no vaccine available.

[1] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002301/
[2] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001623/
[3] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001622/
[4] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002313/
[5] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001859/
[6] http://www.cdc.gov/tularemia/
[7] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002332/
[8] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002388/
[9] http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/ebola.htm
[10] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001624/
[11] http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001676/
[12] http://www.cdc.gov/ncidod/dbmd/diseaseinfo/staphylococcus_food_g.htm
[13] http://www.cdc.gov/melioidosis/index.html
[14] http://www.melioidosis.info/about.aspx#
[15] http://ideas.health.vic.gov.au/bluebook/melioidosis.asp
[16] http://www.vdh.state.va.us/oep/Agents/BiologicalAgents/Agents_Biological_Glanders.htm

Document 6

Congressional Research Service

MEMORANDUM June 7, 2013

To: House Committee on Energy and Commerce
Attention: Alan Slobodin

From: Dana A. Shea, Specialist in Science and Technology Policy, 7-6844
Frank Gottron, Specialist in Science and Technology Policy, 7-5854
Sarah Lister, Specialist in Public Health and Epidemiology, 7-7320

Subject: **Information for a hearing on the Department of Homeland Security BioWatch program**

This memorandum responds to your request for an overview of the Department of Homeland Security (DHS) BioWatch program. You requested information about the history of the BioWatch program; funding appropriated for its development, operation, and maintenance; and policy issues of potential interest to the Committee.

Information in this memorandum is of general interest to Congress. As such, this information may be, or may have been, provided to other congressional requesters, and may be published in CRS products for general distribution to Congress at a later date. Your confidentiality as a requester would be preserved in any case. Please contact us with any questions.

History and Background of the BioWatch Program

The BioWatch program, started in 2003, is responsible for oversight of a system of biological agent or pathogen detectors deployed in order to provide early warning, detection, or recognition of a biological attack. It is located within the DHS Office of Health Affairs (OHA). The BioWatch program is also responsible for acquiring the next-generation of pathogen detectors in order to provide detection continuity and increased technical capabilities.

The BioWatch program has located current-generation BioWatch systems in more than 30 cities. President Bush announced the existence of the BioWatch program during the 2003 State of the Union address.[1] The DHS Science and Technology (S&T) Directorate deployed and oversaw the BioWatch systems from the program's inception until the creation of OHA late in 2007. The DHS then transferred responsibility for the BioWatch program to OHA. The S&T Directorate performed and continues to perform research and development (R&D) into biological detection technologies. The OHA does not have R&D responsibilities.

[1] Executive Office of the President, The White House, *State of the Union Address*, January 28, 2003.

The BioWatch system is composed of biological detectors that monitor the air for the presence of specific pathogens.[2] These detectors collect airborne particles onto filters, which are subsequently transported to laboratories for analysis. It is expected that this system will provide early warning of a pathogen release, alerting authorities of the bioterrorism event before victims begin to show symptoms and providing the opportunity to deliver medical intervention earlier. Computer models constructed by the Department of Health and Human Services and other experts suggest that early response to an airborne biological attack may lead to fewer casualties and fatalities.[3] The DHS used a technology developed at the Department of Energy national laboratories, the Biological Aerosol Sentry and Information System (BASIS), to develop the initial BioWatch systems, known as BioWatch Generation 1, or Gen-1. In 2005, DHS expanded the BioWatch deployment. This expanded deployment included the addition of indoor monitoring capabilities. These systems, which are currently in place, are known as BioWatch Generation 2, or Gen-2. In recent years, DHS has deployed few new Gen-2 BioWatch systems, except for temporary use associated with National Special Security Events. However, DHS requires annual funding to operate and maintain existing Gen-2 systems.

Positive findings from BioWatch samples are termed "BioWatch Actionable Results" (BARs). When this occurs, federal, state, and local officials take steps to determine the appropriate response. They may review findings from adjacent devices, conduct additional tests on samples, and review additional relevant information to determine next steps. In the event of a suspected mass exposure to a bioterrorism agent, state and local public health officials, with federal assistance, are responsible for the public health response.[4] These officials may decide to begin mass prophylaxis of exposed populations and may request medical countermeasures (e.g., drugs and vaccines) from the Strategic National Stockpile (SNS), managed by the Centers for Disease Control and Prevention (CDC).[5] State and local health officials are responsible for mass distribution and dispensing. Through its Cities Readiness Initiative, CDC provides grant funds to 72 major metropolitan areas to strengthen their ability to respond to a large-scale bioterrorist event within 48 hours.[6]

The BioWatch program has not detected a bioterrorism incident since its inception, although it has detected pathogens of concern. Scientists believe that natural airborne "background" levels of these pathogens, or close relatives of them, exist in certain regions. In 2012, the *Los Angeles Times* published a series of investigative articles criticizing the performance of BioWatch.[7] These articles echoed in part the concerns of the Government Accountability Office (GAO)[8] and the National Research Council.[9] The *Los*

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[2] The identities of these pathogens are classified. The GAO has identified that the BioWatch system detects at least five pathogens (Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012).

[3] See, for example, Prasith Baccam and Michael Boechler, "Public Health Response to An Anthrax Attack: An Evaluation of Vaccination Policy Options," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 5, 2007, pp. 26-34; and Lawrence M. Wein, David L. Craft, and Edward H. Kaplan, "Emergency Response to an Anthrax Attack," *Proceedings of the National Academy of Sciences of the United States of America,* Vol. 100, 2003, pp. 4346-4351.

[4] The Federal Bureau of Investigation is responsible for the law enforcement response to a bioterrorism incident.

[5] Centers for Disease Control and Prevention, Strategic National Stockpile, http://www.cdc.gov/phpr/stockpile/stockpile.htm.

[6] Centers for Disease Control and Prevention, Cities Readiness Initiative (CRI), http://www.cdc.gov/phpr/stockpile/cri/index.htm. BioWatch jurisdictions may be among the CRI cities, but CRS cannot confirm this with publicly available information.

[7] David Willman, "The Biodefender that Cries Wolf," *Los Angeles Times*, July 8, 2012.

[8] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

[9] National Research Council, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011.

Angeles Times articles claimed that the BioWatch system is prone to false alarms and is also insufficiently sensitive to detect an actual bioterrorism incident. Dr. Alexander Garza, then the DHS Assistant Secretary for Health Affairs, disputed these claims.[10] In addition, some state and local health officials defended the program, saying, among other things, that it has fostered collaboration among federal, state, and local officials who would be called upon to work together in response to an actual incident.[11]

The systems currently deployed require technicians to collect samples periodically from the geographically distributed devices. These samples generally are brought to local public health laboratories and tested for the presence of biological agents. The lack of sample collection automation and the time required to transport and process samples at local public health laboratories create logistical challenges. In practice, samples from BioWatch systems are processed on a daily basis, though this might be done more frequently with commensurate increases in operational costs. Since soon after the initial deployment of the BioWatch Gen-2 systems, DHS has focused its attention on developing a next-generation BioWatch system with increased automation. Such increased automation might increase the number of samples processed daily and thus reduce the amount of time elapsing between a potential biological release and its detection. The concept of a next-generation BioWatch system became known as BioWatch Generation 3, or Gen-3.

BioWatch Gen-3 has been under development since 2004 by the DHS S&T Directorate.[12] The BioWatch Gen-3 system would include the air sampling and the biological agent detection in the same device. This system is to analyze samples autonomously and remotely report the results. The OHA intends the BioWatch Gen-3 systems to reduce the time to detect a biological agent release from the current 36 hours to less than 6 hours. Shortening the time to detection in this way would allow more time for public health response and a greater likelihood of success in providing medical countermeasures to exposed populations before serious illnesses ensued.

In 2007, DHS established a pilot program as an interim solution to the development of BioWatch Generation 3. Through this pilot program it deployed the Autonomous Pathogen Detection System (APDS), a prototype system developed by Lawrence Livermore National Laboratory in association with private industry. The APDS is sometimes referred to as BioWatch Gen-2.5. The DHS had identified shortcomings in the APDS, including size, efficiency, environmental robustness, and sensitivity, but believed that some of the APDS shortcomings could be minimized through deployment in indoor settings.[13] The DHS halted the APDS pilot deployment when the APDS began malfunctioning in the field.[14]

The DHS has experienced multiple challenges in attempting to develop, test, and acquire the BioWatch Gen-3 system. Initially expected to be deployed in 2012,[15] DHS now estimates Gen-3 deployment

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[10] Dr. Alexander Garza, Assistant Secretary for Health Affairs, DHS, "The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack," blog posting, July 12, 2012.

[11] See, for example, Robert Roos, "Public Health Officials Respond to Critique of BioWatch," *CIDRAP News*, August 17, 2012, http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/aug1712biowatch.html.

[12] Department of Homeland Security, *Department of Homeland Security: Science and Technology Fiscal Year 2006 Congressional Justification*, p. 61.

[13] Jeffery Runge, Department of Homeland Security Assistant Secretary for Health Affairs and Chief Medical Officer, Testimony before the House Committee on Appropriations Subcommittee on Homeland Security, April 1, 2008.

[14] Spencer S. Hsu, "U.S. Halts Pilot Program in New York to Detect Biological Attacks," *Washington Post*, May 7, 2009.

[15] National Research Council, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011, p. 52.

beginning in 2016.[16] The life-cycle cost estimate[17] for the program has increased from $2.1 billion to $5.8 billion.[18] The performance of the BioWatch program has attracted the attention of Members of Congress since its inception. These challenges in acquiring a next-generation system have been the subject of congressional hearings.[19] Congressional appropriators have at times sought to limit funding for program expansion and/or called for program reviews.[20] The BioWatch Gen-3 program is currently undertaking a new Analysis of Alternatives (AoA)[21] for the BioWatch Gen-3 acquisition, as recommended by GAO in 2012.[22] The DHS expects to complete the AoA in 2013. The DHS has stated its intention to decide the future of the BioWatch Gen-3 acquisition in late 2013 following consideration of the AoA results.[23]

Appropriations for the BioWatch Program

From FY2003 through FY2007, the DHS Science and Technology Directorate (S&T) oversaw the BioWatch program. The DHS did not specifically identify funding in the S&T Directorate for BioWatch, instead incorporating it with other biological countermeasures funding. In FY2008, DHS transferred BioWatch operations and management responsibilities from S&T to the Office of Health Affairs (OHA). **Table 1** presents BioWatch funding for OHA since the transfer. BioWatch funding accounts for more than half of the OHA budget.

Table 1. Appropriations for BioWatch in Office of Health Affairs

($ in millions)

FY2008	FY2009	FY2010	FY2011	FY2012	FY2013[a]	FY2014 Request
77.1	111.6	89.5	100.8	114.2	85.3	90.6

Source: CRS analysis of Department of Homeland Security appropriations acts, FY2013 operating plan, and FY2014 budget request, http://www.dhs.gov/dhs-budget.

a. Amount reflects across-the-board rescissions and sequestration.

[16] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

[17] A lifecycle cost estimate is the expected total cost to the government of acquisition and ownership of a system over its useful life. It includes the expected costs of development, acquisition, operations, and support (to include manpower), and where applicable, disposal.

[18] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

[19] For example, U.S. Congress, House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response and Communications, *The Fiscal Year 2013 Budget Request for the Department Homeland Security's Office of Health Affairs*, 112th Cong., 2nd sess., March 29, 2012.

[20] See CRS annual Homeland Security appropriations reports, sections on Office of Health Affairs, for examples. http://crs.gov/pages/subissue.aspx?cliid=2345&parentid=73&preview=False.

[21] An Analysis of Alternatives (AoA) provides a systematic analytic and decision making process to identify and document an optimal solution for an identified mission capability gap. An AoA involves application of analyses that evaluate effectiveness, suitability, and financial justification for each viable alternative. The AoA considers both materiel and non-materiel solutions as well as combinations of non-material and materiel solutions, such as reengineered processes supported by modernized systems.

[22] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

[23] Department of Homeland Security, *BioWatch Gen-3 Phase II, Stage 1 Presolicitation and Draft Request for Proposal*, HSHQDC-13-R-00026, February 8, 2013.

The DHS has not presented BioWatch funding amounts according to generation. However, for FY2007, the House Appropriations Committee urged the S&T Directorate, in report language, to proceed with Gen-3 development.[24] Both chambers reiterated this directive to the S&T Directorate for FY2008, although ongoing BioWatch operations were funded through OHA beginning that year.[25] Beginning with FY2009, congressional appropriators, in report language, expressed concerns regarding Gen-3 development and deployment.[26]

Policy Issues

The BioWatch program faces a wide range of policy challenges. Below are selected issues of potential interest to congressional policymakers. They are organized into three broad categories: strategy, relationship with public health, and acquisition of next-generation systems.

Strategic Issues

Environmental surveillance is a key component of federal strategic planning against biological terrorism.[27] Within these federal biodefense efforts, the BioWatch program is intended to play a central surveillance role, complementing traditional disease reporting efforts and recently developed efforts to use health data to identify disease outbreaks, a process sometimes known as syndromic surveillance. In determining the efficacy of the BioWatch program in meeting the strategic goal of providing warning of a biological terror attack, policymakers may be interested in how the BioWatch program adapts to the changing biological terrorism threat, how DHS determines the population protected through the BioWatch program, and how DHS and other stakeholders respond to BioWatch alarms that do not arise from terrorism.

Risk Assessment and the Evolving Threat

When DHS began BioWatch in 2003, it intended the program to address a range of adversary capabilities regarding biological weapons. For example, in 2004, DHS described the deployment of first-generation BioWatch systems as part of "domestic preparedness during war with Iraq and Al Qaeda,"[28] implying that the program was to address both potential state-sponsored and transnational terrorism. During the existence of the BioWatch program the biological weapon threat has altered due to changing events, such as advances in technology, changes in terrorist capabilities, and changes in political regimes in various countries.

In 2004, President Bush issued Homeland Security Presidential Directive (HSPD) 10, *Biodefense for the 21st Century*, part of which required "a continuous, formal process for conducting routine capabilities assessments to guide prioritization of our on-going investments in biodefense-related research,

[24] H.Rept. 109-476, to accompany H.R. 5441, appropriations for the Department of Homeland Security for FY2007, p. 112, May 22, 2006.

[25] H.Rept. 110-181, p. 92; and S.Rept. 110-84, pp. 88-89.

[26] For more information, see sections on Office of Health Affairs Issues for Congress in CRS Report R42644, *Department of Homeland Security: FY2013 Appropriations*, coordinated by William L. Painter.

[27] White House, *National Strategy for Biosurveillance,* July 2012, p. 5, http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf.

[28] P. L. Estacio, Senior Medical Advisor and BioSecurity Program Executive, Department of Homeland Security, *Bio-Watch Overview*, September 27, 2004.

development, planning, and preparedness."[29] HSPD-10 assigned responsibility for these assessments to DHS. The DHS S&T Directorate has conducted a bioterrorism risk assessment (BTRA) every two years, starting in 2006. While some experts have critiqued the risk methodology used in the BTRA and questioned its use as a planning mechanism,[30] many would agree that it provides a mechanism for assessment and reprioritization of federal capabilities in response to changing adversary capabilities.

In 2012, GAO found that the BioWatch program generally incorporated BTRA information and aligned its detection capabilities against the biological agents of significant concern (as identified in the BTRA). In addition, DHS has stated that the expanded number of biological threat agents to be detectable by future generations of BioWatch systems will be informed by the BTRA's risk rankings.[31] Policymakers may be interested in the extent to which the DHS bioterrorism risk assessment has determined the technical requirements of the Gen-3 system and the capabilities of the Gen-3 system to evolve and respond to the potential changing threat.

Population Coverage

The DHS deployed the BioWatch Gen-2 systems in urban environments with high population density. Each BioWatch system provides detection capability for some fraction of the population. Deployment of BioWatch systems might be viewed as a tradeoff between the detection coverage and the costs of such deployment. More detectors provide greater population coverage but with increasing cost. However, as population density decreases (often with increasing distance from the center of a city), each additional system provides a smaller increase in coverage for the same increase in cost. The DHS goal for BioWatch Gen-2 population coverage within a BioWatch jurisdiction was 80%,[32] but apparently only 65% coverage exists.[33] Assuming that DHS places existing detectors in each jurisdiction's most population-dense areas, it would be more costly to cover an additional 15% of the jurisdiction's target population (in less dense areas) than it was to provide any 15% increment of existing coverage.

The DHS set a population coverage goal for the BioWatch Gen-3 system of 90% of the population within a BioWatch jurisdiction, an increase relative to the existing BioWatch Gen-2 system. The GAO reported that the BioWatch Gen-3 system deployment would increase the number of BioWatch jurisdictions, the number of systems per jurisdiction, the total U.S. population covered, and the population coverage in BioWatch jurisdictions.[34] It is unknown whether BioWatch Gen-3 will have a gap between the population coverage goal and the actual coverage similar to the BioWatch Gen-2 gap, especially since DHS has not identified a final technology for the system.

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[29] The White House, *Biodefense for the 21st Century*, Homeland Security Presidential Directive (HSPD) 10, April 28, 2004.

[30] National Research Council, Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, *Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change*, National Academies Press, Washington, DC, 2008.

[31] Government Accountability Office, *Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use*, GAO-12-272, January 2012, pp. 26-27.

[32] Office of Inspector General, Environmental Protection Agency, *EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program*, 2005-P-00012, March 23, 2005, p. 4.

[33] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 21.

[34] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 22.

The population coverage in each BioWatch jurisdiction likely depends upon the number of detectors deployed and the modeling and assumptions used regarding the transport of biological agents from their point of release to the detector. As a consequence, coverage areas and populations affected likely depend on the type of pathogen released. For example, estimates of detection coverage are likely larger for a pathogen that can travel further in viable form (e.g., a spore-former such as *Bacillus anthracis*) than for a pathogen that cannot. Similarly, detector performance and pathogen transport behavior likely affect the minimum quantity of a released pathogen that can be detected. As a consequence, performance of the BioWatch system likely varies depending on the type of biological agent and expectations regarding how the adversary will use the agent.

The GAO and others have identified challenges in the use of plume modeling in urban environments, although federal agencies have attempted to consolidate and coordinate such modeling efforts.[35] Such plume modeling is key to predicting the likelihood that a biological release will be detected and to determine the extent of exposure and the prophylaxis distribution plan. Accurate models allow for estimates of detectable release amounts, the number of detectors needed for coverage of a given area, and subsequent response to a detection event.

Policymakers may be interested in identifying the range of threats that DHS expects the BioWatch Gen-2 and Gen-3 systems to detect. For example, policymakers may view a system able to detect only large aerosol releases as having a different value than one also able to detect small-scale attacks.

Definition of a False Positive

A system designed to detect just one type of threat can be characterized by two numbers:

- the true positive rate, or probability of detection, which is defined as the probability that the system will detect a threat when one is present; and
- the false positive rate, or false alarm rate, which is defined as the probability that the system will indicate a threat when *no* threat is present.

Each of these characteristics can also be described by its complement:

- the false negative rate, which is defined as the probability that the system will *not* detect a threat when one is present (this is 100% minus the true positive rate); and
- the true negative rate, which is defined as the probability that the system will *not* indicate a threat when no threat is present (this is 100% minus the false positive rate).

Table 2 illustrates these definitions.

[35] For an overview of challenges identified by GAO and interagency groups, see Government Accountability Office, *Homeland Security: First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas Is Significantly Limited*, GAO-08-180, June 2008.

Table 2. Terms Used to Describe Detector Performance for a Single Threat

Actual	Alarm	No Alarm
Threat	True Positive	False Negative
No Threat	False Positive	True Negative

Source: CRS

The use of the term *false positive* is potentially confusing when discussing the BioWatch program, as it has referred specifically to the act of detection rather than the context for the detection. The BioWatch program is intended to detect biological terrorism, but some of the pathogens under detection also naturally exist in the environment. According the DHS, the events identified by the National Research Council and the *Los Angeles Times* as false positives were actually correct identifications of the biological agent, but these pathogens either arose from natural circumstances or are similar, naturally occurring, non-pathogenic versions of the biological agents. The National Research Council report acknowledges this difference, and identifies a new term, a "BioWatch Actionable Result (BAR) false positive," to address false positives in the BioWatch context:

> Indeed, the laboratory assays have never indicated the presence of a biological agent when it was not present, although several BARs have been declared that have been attributed to the detection of ambient DNA that was naturally present in the local environment. 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.[36]

When one considers the number of BAR false positives relative to the number of potential detection events (samples analyzed), the false positive rate is quite low, estimated at approximately 1 in 189,000 events.[37] Such a false positive rate meets or exceeds requirements for other homeland security detection systems.[38] Some policymakers might view such a false positive rate as acceptable given the limits of comparable technology. Other policymakers might view any number of BAR false positives as unacceptable, since the desired response to a BioWatch Actionable Result is to begin early treatment of potentially exposed individuals. Such early treatment may involve activation of federal assets such as the Strategic National Stockpile; notification of the public regarding necessary treatments; and the initiation of law-enforcement activities. In contrast to the response to alarms from other detectors used for homeland security, these activities come with both a financial and social cost that some policymakers may view as too expensive for a false alarm.

[36] National Research Council, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011, pp. 50-51.

[37] CRS analysis based on data reported in Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer for DHS, "The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack," *The Blog@Homeland Security*, July 12, 2012, http://blog.dhs.gov/2012/07/truth-about-biowatch-importance-of.html.

[38] For example, the testing and evaluation protocol for certain radiation detection systems requires a false alarm rate of less than 1 in 1,000. National Institute of Standards and Technology, *Testing and Evaluation Protocol for Spectroscopy-Based Portal Monitors Used for Homeland Security*, T&E Protocol N42.38, Version 1.02, 2010.

External Reviews

External groups have studied the BioWatch system and provided advice to DHS. These include the National Research Council of the National Academies (NRC),[39] GAO,[40] Sandia National Laboratories, and the Homeland Security Studies and Analysis Institute.[41]

In 2009, the NRC provided DHS with the findings of its study, although the final report was not published until 2011.[42] The NRC found it difficult to determine the effectiveness of the BioWatch Gen-2 system due to insufficient testing by DHS. It also found that performance of the system could be improved through better DHS collaboration with local public health jurisdictions. Additionally, the NRC found that DHS would need to overcome significant scientific and technical hurdles to successfully develop Gen-3 detectors.

In September 2012, GAO published its report to Congress on BioWatch Gen-3 development. The GAO found deficiencies in the DHS Gen-3 acquisition process. It found some key documents used to support acquisition decisions, such as the Mission Need Statement[43] and the Analysis of Alternatives, appeared to have been written to fit predetermined findings rather than using objective analysis.[44] The GAO recommended that DHS reevaluate its biosurveillance needs and then complete an objective analysis of several possible solutions to address the identified capabilities gap. The DHS did not comment in the GAO report whether it planned to complete a new Mission Needs Statement.[45] However, the DHS expects the new Analysis of Alternatives to be completed in fall 2013. Some of the alternatives that DHS could consider include other technical approaches, varying the number of planned detectors and population coverage, continued use of Gen-2 systems as currently deployed or modified, or ending the BioWatch program. However, the DHS has not stated what options it has included in its analysis.

The DHS commissioned at least two studies that are not publicly available. According to GAO, Sandia National Laboratories evaluated the requirements set by DHS regarding the level of Gen-3 pathogen sensitivity. This study led DHS to relax its technical requirements regarding the Gen-3 pathogen sensitivity.[46] The Homeland Security Studies and Analysis Institute was to evaluate whether the Gen-3 technology is mature enough to proceed to acquisition or whether it needs additional development work,

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[39] National Research Council, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011.

[40] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

[41] The Homeland Security Studies and Analysis Institute and Sandia National Laboratories studies are not publicly available.

[42] National Research Council, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011, p.1.

[43] A Mission Need Statement is a high-level document whose primary purpose is to clearly define and articulate an identified capability need/gap. It describes the mission need in sufficient detail for reviewers to understand the need for the specific capabilities required to perform a mission. It is intended to provide the basis on which the reviewers can decide whether to initially authorize an acquisition program or project.

[44] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p.18.

[45] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 41.

[46] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 28.

as the NRC had found previously.[47] The extent to which DHS has incorporated the findings of these reports into its acquisition decision making process is difficult to assess because these reports are not publicly available.

Intersection with Public Health

The success of the BioWatch program relies heavily on its use by state and local public health officials, who have the primary authority and responsibility for public health decisions in their jurisdiction. The confidence of these officials in the performance of existing BioWatch Gen-2 and the potential autonomous Gen-3 systems relies on multiple factors, including the robustness of concepts of operation; the extent of trust and experience between federal, state, and local stakeholders; and the rigor of the detection technology underlying the BioWatch systems.

Concepts of Operation and Local Jurisdiction Participation

In the current BioWatch Gen-2 configuration, local jurisdictions, which are the principal responders to a BAR, play a key role in the program. (See **Figure 1**.) They collect and analyze BioWatch samples and determine whether a result is positive. Local officials need to have sufficient confidence in the BioWatch system to make difficult and potentially economically costly decisions following a positive BioWatch result. However, media coverage over the past year has raised questions regarding local jurisdictions' confidence in the current BioWatch Gen-2 system.[48]

If a positive BioWatch result signaled an actual or potential mass exposure to a bioterrorism agent, public officials would have to consider a number of potentially high-regret decisions. Those responsible for public safety may weigh decisions to close major transportation hubs or cordon off large numbers of dwellings or businesses. It falls to public health officials to determine if mass medical treatment of potentially exposed populations should be carried out, and if they so determine, to carry out this task under substantial time pressure.

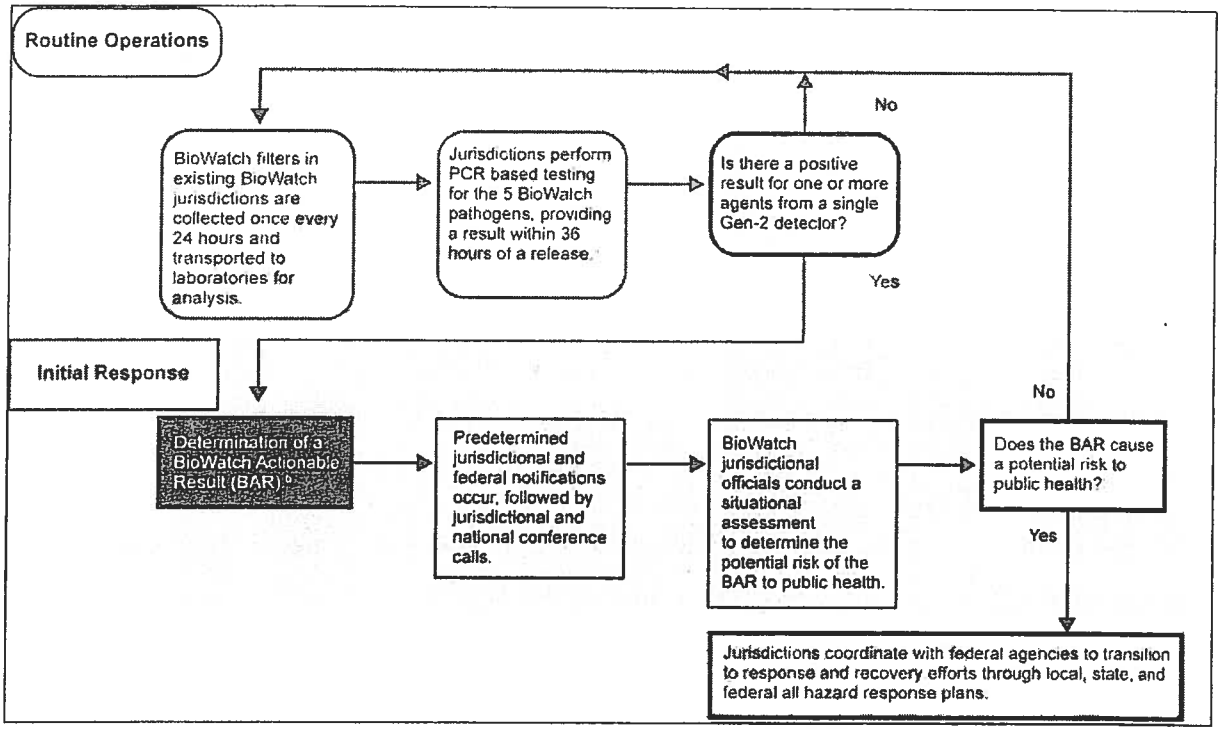
The Laboratory Response Network for Bioterrorism (LRN), coordinated by CDC, also supports testing for bioterrorism agents. Certain member laboratories (most of them governmental) test both environmental samples (e.g., white powders) and clinical samples (e.g., blood). LRN tests are non-commercial and are generally developed and delivered by CDC to network participants.[49] CDC provides ongoing technical support to LRN member laboratories conducting bioterrorism testing. Many of them are state and local public health laboratories. BioWatch Gen-2 testing is an LRN activity.

[47] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 23.

[48] For example, see David Willman, "The Biodefender That Cries Wolf," *Los Angeles Times*, July 8, 2012.

[49] Department of Health and Human Services, Centers for Disease Control and Prevention, "Facts About the Laboratory Response Network," http://emergency.cdc.gov/lrn/factsheet.asp.

Figure 1. Role of Jurisdictions in BioWatch (Gen-2)



Source: CRS modified from Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 11.

a. Polymerase chain reaction (PCR) is a technique to copy DNA for laboratory testing.

b. The BioWatch program defines a BAR as one or more PCR-verified positive results from a single BioWatch detector.

As noted, in the current BioWatch Gen-2 configuration, local public health officials are generally involved in sample analysis. They are, therefore, the first to know if a sample is positive and are actively involved in determining whether such a finding signals an actionable incident. Under an autonomous analysis system such as BioWatch Gen-3, local officials would no longer be responsible for sample analysis; such a change could affect their confidence in BioWatch results. OHA officials told GAO that they "want the jurisdictions to have enough confidence in the system that they are willing to take action based on positive results from a Gen-3 system without confirmatory laboratory testing."[50]

Some of the confidence local jurisdictions have in Gen-2 likely arises from their familiarity through extensive use of the system. To help instill local confidence in the Gen-3 system DHS told GAO

> they provide guidance to jurisdictions and are in the process of developing a quality assurance process to track system performance. Furthermore, these officials anticipate running Gen-2 and Gen-3 concurrently for up to 6 months in BioWatch jurisdictions, and requiring all candidate technologies to

[50] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

archive positive samples so that the jurisdictions can run confirmatory laboratory analysis on the samples.[51]

One of the key possible benefits of Gen-3 technology over Gen-2 technology is the decrease in time between the biological release and the signaling of a positive result. However, local officials who lack sufficient trust in the results from the autonomous detectors may delay the politically difficult and potentially economically costly decisions until the results are confirmed by a methodology in which they have greater confidence. Such a course of action could significantly reduce the benefits from acquiring Gen-3 technology. Given the importance of local jurisdiction confidence in the new technology, it is unclear whether the confidence building efforts DHS has outlined will prove sufficient.

Assay Performance[52]

The decision to conduct mass medical treatment in a potentially exposed population involves administering drugs, vaccines, and/or treatments. These are medical (i.e., clinical) decisions. In order to assure reliable performance of medical tests, the federal government regulates clinical laboratory testing in two ways. The Food and Drug Administration (FDA) requires demonstration of a test's efficacy in routine use in order for the test to be licensed for use. In addition, the Centers for Medicare and Medicaid Services (CMS), pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), certifies laboratories that conduct clinical testing as being able to do so reliably.[53]

BioWatch assays are not required to conform to these federal standards, and it is not clear that they could conform. A key element in quality assurance, both for test method performance and laboratory performance, is assessment of an assay against a "gold standard," a rigorous test with known performance characteristics. Gold standard tests are often too costly, cumbersome, or slow for routine or screening uses. Instead they are used to assess the reliability of rapid screening tests, for example, and to confirm their findings. In clinical microbiology, testing often involves assays of microbial chemicals or genetic material (DNA or RNA) to determine the presence of the organism. The gold standard is subsequent growth of the organism ("culture confirmation"), confirming the accuracy of the positive chemical or DNA screening test. In the context of BioWatch microbial testing, confirmatory culture is often not possible; pathogens may dry out and become non-viable in the sensors. Also, the time required for culture confirmation would come at the expense of the early warning capability that is the key purpose of BioWatch.

If the BioWatch assays met an alternate set of meaningful benchmarks, public health decision-makers' trust in the assays could potentially increase, even without the benefits of FDA approval, CLIA oversight, and confirmatory testing. The DHS S&T Directorate is interested in developing consensus standards for microbial field tests that are intended to be actionable by public safety officials (i.e., guiding decisions to evacuate, close, or cordon) and actionable by public health officials (i.e., guiding decisions regarding mass prophylaxis or quarantine.)[54] Such standards would include general elements, such as a concept of

[51] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

[52] An assay is an analysis used to determine the presence (and sometimes also the amount) of a chemical or substance of interest in a sample. An assay includes both physical components, such as treated filters and liquid reagents, and the procedures used in performing the assay.

[53] P.L. 100-578. See Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Clinical Laboratory Improvement Amendments," http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

[54] Department of Homeland Security, Science and Technology Directorate, *Framework for a BioThreat Field Response Mission Capability*, April 5, 2011, p. 7.

operations, and specific elements, such as characteristics (e.g., DNA sequences) that definitively identify each biothreat agent of interest.

Acquisition of Next-Generation Systems

The DHS has attempted to acquire next-generation BioWatch systems since 2009. This acquisition has had multiple challenges, including questions regarding the benefits and costs of the system. While DHS has received appropriations to acquire a next-generation system, DHS has not yet acquired such a system. Instead, most funds have been invested in testing and evaluating prototype systems that did not meet system requirements. In this context, policymakers have questioned the evolution of technical analyses and requirements and the viability of the current acquisition process.

BioWatch Gen-3 Costs and Benefits

The DHS acquisition process, as defined in DHS acquisition management directive 102-01, is a multistep process with specific associated acquisition decision events.[55] DHS acquisition policy requires development of certain analysis and documentation for programs with lifecycle costs above specified thresholds. Within these requirements are assessments of alternative approaches and estimates of the costs and benefits of the proposed acquisition. Even in cases where costs or benefits cannot be quantified, "breakeven" or threshold analysis might be performed. As described by the White House Office of Information and Regulatory Affairs:

> When quantification and monetization are not possible, many agencies have found it both useful and informative to engage in threshold or "breakeven" analysis. This approach answers the question, "How large would the value of the non-quantified benefits have to be for the rule to yield positive net benefits?"[56]

The GAO has reported that DHS did not fully assess the costs and benefits of the BioWatch Gen-3 program. The DHS performed a limited cost analysis and did not analyze or identify specific benefits beyond those accruing from early detection. The GAO identified that these analyses were limited because within DHS "consensus already existed that autonomous detection was the optimal solution."[57] A key question for policymakers is whether the costs of the Gen-3 acquisition, or even the BioWatch program as a whole, are worth the benefits received.

Costs

The BioWatch Gen-3 acquisition has had challenges regarding the program's overall costs and maintaining target cost goals. The GAO has reported that key DHS goals for the BioWatch Gen-3 program included "to deploy in all major cities an autonomous BioWatch detection device reducing the operating cost per site by more than 50 percent and warning time to less than 6 hours."[58] The detection

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[55] Department of Homeland Security, *Acquisition Management Directive*, 102-01, undated, http://www.dhs.gov/xlibrary/assets/foia/mgmt_directive_102-01_acquisition_management_directive.pdf.

[56] Office of Information and Regulatory Affairs, The White House, *Regulatory Impact Analysis: A Primer*, undated, http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf. See also U.S. Office of Management and Budget, *Circular A-4*, September 17, 2003.

[57] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 20.

[58] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before* (continued...)

system tested by the BioWatch Gen-3 program does not reduce the operating cost per detector. Consequently, replacing BioWatch Gen-2 systems with an equivalent number of BioWatch Gen-3 systems would itself lead to a more expensive BioWatch program.

In addition, GAO reports that DHS plans to increase both the number of BioWatch jurisdictions and the number of detectors per jurisdiction. Thus, the envisioned BioWatch Gen-3 program would deploy a greater number of detectors than currently deployed under Gen-2. The GAO asserts this deployment would have a Gen-3 annual operating cost approximately four times greater than the current BioWatch Gen-2 program.[59]

Further, the estimated lifecycle costs of the BioWatch Gen-3 program increased between 2009 and 2011 from $2.1 billion to $5.8 billion.[60] According to the GAO, prior cost estimates "did not account for risk and uncertainty, and it was not based on the work breakdown structure for Gen-3 and as such, DHS did not have assurance that it captured all relevant costs."[61] In contrast to the estimate from 2009, the 2011 estimate captures relevant costs, includes the full expected lifecycle of the Gen-3 system, and is adjusted for risk and uncertainty.[62] The $5.8 billion estimate in 2011 has an 80% confidence level, meaning there is an 80% likelihood that the lifecycle cost will not exceed $5.8 billion.[63] For comparison purposes, DHS provides an estimate at the 28% confidence level that the lifecycle cost will not exceed $3.8 billion.

Benefits

The GAO found that DHS planning documents for BioWatch Gen-3, specifically the Analysis of Alternatives, failed to "identify any benefits of investment beyond the assumption—inherent in its focus on increasing the number of detection cycles per day—that earlier detection has the potential to save lives and limit economic loss, a basic and accepted principle for all enhanced surveillance efforts."[64] The GAO identified at least four metrics that DHS could include in estimates of the benefits of acquiring, deploying, and operating the BioWatch Gen-3 system:

- risk reduction per additional BioWatch jurisdiction;
- risk reduction per fraction of U.S. population covered;
- risk reduction per fraction of BioWatch jurisdiction population covered; and
- risk reduction per hour of detection time.

(...continued)

Proceeding with BioWatch Generation-3 Acquisition, GAO-12-810, September 2012, p. 16.

[59] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 22.

[60] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

[61] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 30.

[62] Note the 2011 cost estimate considers costs through FY2028, while the 2009 cost estimate considers costs through FY2020 (Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 31).

[63] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

[64] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

The DHS might take other approaches to estimating benefits, such as determining the results from various attack scenarios, determining the beneficial impacts arising from the presence of the BioWatch system, and attempting to convert these benefits into monetary terms. The U.S. Coast Guard took such an approach, for example, when determining the benefits from mandating implementation of electronic Transportation Worker Identification Credential (TWIC) readers.[65]

Another potential factor for policymaker consideration is the increasing age of the BioWatch Gen-2 systems. The DHS deployed BioWatch systems beginning in 2003, and these systems may be reaching or surpassing their expected life-span. In general, as systems approach their design life-span, operation and maintenance costs increase. Often, replacement of these systems becomes more cost-effective, over the long term, than continued maintenance of aging systems. A potential benefit from deploying a BioWatch Gen-3 system would be the avoided cost of recapitalizing BioWatch Gen-2 systems. The DHS has not publicized the contents of the program AoA to be completed in 2003, its range of costs and benefits considered, and the alternatives analyzed.

Requests for Proposals

The DHS effort to acquire a BioWatch Gen-3 system that meets the technical requirements established by OHA has relied on a series of DHS requests for information and proposals from vendors that have systems that might meet the Gen-3 technical requirements. Few vendors have participated, and Congress has expressed concern regarding the range of competition present in BioWatch Gen-3 acquisition.[66] In addition, DHS has delayed acquisition and deployment of BioWatch Gen-3 systems as the program has evolved.

Initially, DHS identified a two-phase approach to acquiring a BioWatch Gen-3 system. First, DHS would engage in independent testing of multiple bio-detectors. Then, following that testing, DHS would issue a single acquisition contract for the successful Gen-3 technology. The DHS began the first phase (Independent Testing of Bio-detectors) of the BioWatch Gen-3 acquisition in 2009.[67] Five vendors responded to the DHS request for proposals (RFP), and DHS provided contracts to two of them. Following the testing and evaluation of these candidate systems, neither system met all key performance parameters required for the Gen-3 acquisition. Only one system, the Next-Generation Automated Detection System (NG-ADS), completed the first round of testing and remains a potential candidate technology.

In February 2011, DHS issued a new request for information (RFI) regarding vendors with systems able to provide BioWatch Gen-3 capabilities.[68] According to then-DHS Assistant Secretary for Health Affairs and Chief Medical Officer Alexander Garza, replies from the RFI indicated that two vendors might have systems capable of responding to a request for proposals.[69]

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[65] 78 *Federal Register* 17782-17833 (March 22, 2013), at 17821-17824. See also U.S. Coast Guard, *Transportation Worker Identification Credential (TWIC) - Reader Requirements Notice of Proposed Rulemaking Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis*, USCG-2007-28915, February 2013.

[66] House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, "Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security," *Serial No. 112-12*, March 17, 2011, p. 19.

[67] Department of Homeland Security, *BioWatch Gen-3 Industry Day*, March 6, 2009.

[68] Department of Homeland Security, *DHS BioWatchGen3 - Phase II*, PHASEIIRFI-2172011, February 17, 2011.

[69] House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, "Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security," *Serial No. 112-12*, March 17, (continued...)

In August 2011, DHS issued a draft RFP for the second phase (System Production, Deployment, Operations, Supply Support, and Maintenance) of the Gen-3 acquisition. Under the draft RFP, DHS would issue a single contract for a technology that met the operation requirements for the Gen-3 system. At that time, DHS expected to issue a final Request for Proposals (RFP) in October 2011 and award acquisition contracts in May 2012.[70] The DHS testified that it considered this acquisition "low risk because of the technology maturity required to be accepted."[71]

In September 2012, DHS revised its acquisition strategy to include a two-step competitive process rather than issuing a single contract. Under this two-step process, candidate technologies would undergo a round of performance testing, similar to that engaged in during 2010-2011 as part of the first acquisition phase. Following this testing, DHS would issue an acquisition contract. In January 2013, DHS issued a new draft RFP as part of the two-step competitive process. The DHS expects to release a final RFP and contract in the third quarter of FY2013.[72] According to GAO, DHS would begin deployment of Gen-3 systems in 2016.[73]

Some policymakers may question the appropriateness of the Gen-3 requirements given the extent of industry participation in the RFP process and the lack of successful candidate systems. Few industry participants may indicate too stringent requirements that outstrip current capabilities. Some policymakers may question the repeated delays in the Gen-3 acquisition timeline and the impacts of these changes in acquisition strategy.

Technical Requirements

The technical requirements for the Gen-3 detectors, known as Key Performance Parameters (KPPs), have changed over time. These KPPs are the threshold requirements, or the minimum standard DHS determined that candidate technologies had to meet to achieve the program goal. In the 2008 Operational Requirements Document, the minimum requirements for BioWatch Gen-3 included the detection of 6 different agents at 10 particles per cubic meter and a false positive rate of 1 in 100 million.[74] According to the GAO, in 2009 the Gen-3 KPPs included the detection of fewer agents (5), at the higher concentration, (60 particles per cubic meter) and higher false positive rate (1 in 10 million). According to GAO, OHA is making additional changes to the Gen-3 KPPs following the failure of the candidate system to meet some KPPs during testing in 2010 and 2011.[75] According to GAO, the candidate system did not meet the pathogen sensitivity requirement and required more frequent maintenance than planned.[76]

(...continued)

2011, p. 19.

[70] Department of Homeland Security, *BioWatch Gen-3 Phase II Industry Day*, September 12, 2011.

[71] House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, "Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security," *Serial No. 112-12*, March 17, 2011, p. 19.

[72] Department of Homeland Security, *BioWatch Gen-3 Phase II, Stage 1 Presolicitation and Draft Request for Proposal*, HSHQDC-13-R-00026, February 8, 2013.

[73] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

[74] Office of Health Affairs, *BioWatch Gen-3 Detection System Operational Requirements Document*, January 24, 2008.

[75] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p.48.

[76] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 48.

To date, DHS has based its acquisition decisions on analyses using technical requirements more stringent than the current ones. It is not clear how the more easily achievable standards will affect the DHS analysis. A sufficient reduction in the Gen-3 system's detection capability could reduce the benefits of the system enough that other alternative solutions become acceptable to DHS. Similarly, increased system operating costs caused by more frequent maintenance could shift cost considerations to favor other alternatives. The DHS has not stated whether the ongoing Analysis of Alternatives due in fall 2013 relies on new or preexisting requirements.

The GAO raised issues with regard to DHS testing for some of the KPPs. The GAO stated that legal restrictions prevented DHS from testing one of the BioWatch agents (GAO did not identify the particular agent in its publicly available report). Another KPP that would be difficult to test prior to acquisition decisions is the probability of false positives. To test that a detector would not signal the presence of an agent when none was present less than once per 10 million tests would require 33.5 years.[77] Policymakers may question the utility of such untestable requirements and the implications of basing acquisition decisions on them.

Coordination of R&D and Acquisition

Initially, DHS received appropriations for the BioWatch program in the S&T Directorate, which operated BioWatch systems and attempted to develop the next-generation successor to it. Following the creation of OHA, Congress provided appropriations to both the S&T Directorate, for R&D of biological detectors, and OHA, for operation of the BioWatch program and acquisition of Gen-3.

The S&T Directorate did not present BioWatch operations funding separately in its budget request. According to the DHS Office of Legislative Affairs, the S&T Directorate spent approximately $160 million between FY2004 and FY2008 to develop potential BioWatch Gen-3 systems.[78] One technology developed by the S&T Directorate, called the Bioagent Autonomous Network Detector (BAND), competed to be a BioWatch Gen-3 candidate technology but did not meet the required performance measures.[79]

The GAO estimates that OHA spent $104 million on BioWatch Gen-3 acquisition from FY 2007 to FY2011, approximately 27% of its total BioWatch funding for that time period.[80] In addition to operating and maintaining BioWatch Gen-2 systems, the OHA also deployed an interim BioWatch solution, the Autonomous Pathogen Detection System (APDS), sometimes referred to as BioWatch Gen-2.5. The DHS halted the APDS pilot deployment when the APDS began malfunctioning in the field.[81] The remaining BioWatch Gen-3 candidate technology under consideration is the Next-Generation Automated Detection System (NG-ADS), a system based upon the Autonomous Pathogen Detection System (APDS).

Policymakers may identify this situation as a problem in coordination and sharing expertise and technical knowledge between the S&T Directorate and OHA. Some policymakers may question the investments

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[77] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 48.

[78] Personal communication between CRS and DHS Office of Legislative Affairs, August 13, 2012.

[79] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 46.

[80] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

[81] Spencer S. Hsu, "U.S. Halts Pilot Program in New York to Detect Biological Attacks," *Washington Post*, May 7, 2009.

made by the S&T Directorate regarding Gen-3 BioWatch. While the S&T Directorate attempted to develop a BioWatch replacement system, its investments did not lead to a successor system. In this light, policymakers may assess this as an R&D failure, with the S&T Directorate failing to incorporate operational requirements into its R&D activities. Similarly, policymakers may question the investments made by OHA. While the OHA has spent at least $104 million on Gen-3 acquisition,[82] no system has met the technical requirements established by OHA. Some policymakers might perceive this as an overly optimistic assessment by OHA of the maturity and capabilities of existing technology.

If you have further questions, please feel free to contact any of the authors directly.

[82] Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, Highlights page.

Document 7

latimes.com/news/nationworld/nation/la-na-biowatch-20120708,0,5093512.story

latimes.com

The biodefender that cries wolf

The Department of Homeland Security's BioWatch air samplers, meant to detect a terrorist biological attack, have been plagued by false alarms and other failures.

By David Willman, Los Angeles Times

July 8, 2012

DENVER — As Chris Lindley drove to work that morning in August 2008, a call set his heart pounding.

The Democratic National Convention was being held in Denver, and Barack Obama was to accept his party's presidential nomination before a crowd of 80,000 people that night.

The phone call was from one of Lindley's colleagues at Colorado's emergency preparedness agency. The deadly bacterium that causes tularemia — long feared as a possible biological weapon — had been detected at the convention site.

Should they order an evacuation, the state officials wondered? Send inspectors in moon suits? Distribute antibiotics? Delay or move Obama's speech?

Another question loomed: Could they trust the source of the alert, a billion-dollar government system for detecting biological attacks known as BioWatch?

Six tense hours later, Lindley and his colleagues had reached a verdict: false alarm.

BioWatch had failed — again.

President George W. Bush announced the system's deployment in his 2003 State of the Union address, saying it would "protect our people and our homeland." Since then, BioWatch air samplers have been installed inconspicuously at street level and atop buildings in cities across the country — ready, in theory, to detect pathogens that cause anthrax, tularemia, smallpox, plague and other deadly diseases.

But the system has not lived up to its billing. It has repeatedly cried wolf, producing dozens of false alarms in Los Angeles, Detroit, St. Louis, Phoenix, San Diego, the San Francisco Bay Area and elsewhere, a Los Angeles Times investigation found.

Worse, BioWatch cannot be counted on to detect a real attack, according to confidential government test results and computer modeling.

The false alarms have threatened to disrupt not only the 2008 Democratic convention, but also the 2004 and 2008 Super Bowls and the 2006 National League baseball playoffs. In 2005, a false alarm in Washington prompted officials to consider closing the National Mall.

Federal agencies documented 56 BioWatch false alarms — most of them never disclosed to the public — through 2008. More followed.

The ultimate verdict on BioWatch is that state and local health officials have shown no confidence in it. Not once have they ordered evacuations or distributed emergency medicines in response to a positive reading.

Federal officials have not established the cause of the false alarms, but scientists familiar with BioWatch say they appear to stem from its inability to distinguish between dangerous pathogens and closely related but nonlethal germs.

BioWatch has yet to face an actual biological attack. Field tests and computer modeling, however, suggest it would have difficulty detecting one.

In an attack by terrorists or a rogue state, disease organisms could well be widely dispersed, at concentrations too low to trigger BioWatch but high enough to infect thousands of people, according to scientists with knowledge of the test data who spoke on condition of anonymity.

Even in a massive release, air currents would scatter the germs in unpredictable ways. Huge numbers of air samplers would have to be deployed to reliably detect an attack in a given area, the scientists said.

Many who have worked with BioWatch — from the Army general who oversaw its initial deployment to state and local health officials who have seen its repeated failures up close — call it ill-conceived or unworkable.

"I can't find anyone in my peer group who believes in BioWatch," said Dr. Ned Calonge, chief medical officer for the Colorado Department of Public Health and Environment from 2002 to 2010.

"The only times it goes off, it's wrong. I just think it's a colossal waste of money. It's a stupid program."

Officials at the Centers for Disease Control and Prevention, the federal agency that would be chiefly responsible for rushing medications to the site of an attack, told White House aides at a meeting Nov. 21 that they would not do so unless a BioWatch warning was confirmed by follow-up sampling and analysis, several attendees said in interviews.

Those extra steps would undercut BioWatch's rationale: to enable swift treatment of those exposed.

Federal officials also have shelved long-standing plans to expand the system to the nation's airports for fear that false alarms could trigger evacuations of terminals, grounding of flights and needless

panic.

BioWatch was developed by U.S. national laboratories and government contractors and is overseen by the Department of Homeland Security. Department officials insist that the system's many alerts were not false alarms. Each time, BioWatch accurately detected some organism in the environment, even if it was not the result of an attack and posed no threat to the public, officials said.

At the same time, department officials have assured Congress that newer technology will make BioWatch more reliable and cheaper to operate.

The current samplers are vacuum-powered collection devices, about the size of an office printer, that pull air through filters that trap any airborne materials. In more than 30 cities each day, technicians collect the filters and deliver them to state or local health labs for genetic analysis. Lab personnel look for DNA matches with at least half a dozen targeted pathogens.

The new, larger units would be automated labs in a box. Samples could be analyzed far more quickly and with no need for manual collection.

Buying and operating the new technology, known as Generation 3, would cost about $3.1 billion over the next five years, on top of the roughly $1 billion that BioWatch already has cost taxpayers. The Obama administration is weighing whether to award a multiyear contract.

Generation 3 "is imperative to saving thousands of lives," Dr. Alexander Garza, Homeland Security's chief medical officer, told a House subcommittee on March 29.

But field and lab tests of automated units have raised doubts about their effectiveness. A prototype installed in the New York subway system in 2007 and 2008 produced multiple false readings, according to interviews with scientists. Field tests last year in Chicago found that a second prototype could not operate independently for more than a week at a time.

Most worrisome, testing at the Pacific Northwest National Laboratory in Washington state and at the Army's Dugway Proving Ground in Utah found that Generation 3 units could detect a biological agent only if exposed to extremely high concentrations: hundreds of thousands of organisms per cubic meter of air over a six-hour period.

Most of the pathogens targeted by BioWatch, scientists said, can cause sickness or death at much lower levels.

A confidential Homeland Security analysis prepared in January said these "failures were so significant" that the department had proposed that Northrop Grumman Corp., the leading competitor for the Generation 3 contract, make "major engineering modifications."

A spokesman for the department, Peter Boogaard, defended the performance of BioWatch. Responding to written questions, he said the department "takes all precautions necessary to minimize the occurrence of both false positive and false negative results."

"Rigorous testing and evaluation" will guide the department's decisions about whether to buy the Generation 3 technology, he said.

Representatives of Northrop Grumman said in interviews that some test results had prompted efforts to improve the automated units' sensitivity and overall performance.

"We had an issue that affected the consistency of the performance of the system," said Dave Tilles, the company's project director. "We resolved it. We fixed it.... We feel like we're ready for the next phase of the program."

In congressional testimony, officials responsible for BioWatch in both the Bush and Obama administrations have made only fleeting references to the system's documented failures.

"BioWatch, as you know, has been an enormous success story," Jay M. Cohen, a Homeland Security undersecretary, told a House subcommittee in 2007.

In June 2009, Homeland Security's then-chief medical officer, Dr. Jon Krohmer, told a House panel: "Without these detectors, the nation has no ability to detect biological attacks until individuals start to show clinical symptoms." Without BioWatch, "needless deaths" could result, he said.

Garza, the current chief medical officer, was asked during his March 29 testimony whether Generation 3 was on track. "My professional opinion is, it's right where it needs to be," he said.

After hearing such assurances, bipartisan majorities of Congress have unfailingly supported additional spending for BioWatch.

Olympic prototype

The problems inherent in what would become BioWatch appeared early.

In February 2002, scientists and technicians from Lawrence Livermore National Laboratory deployed a prototype in and around Salt Lake City in preparation for the Winter Olympics. The scientists were aware that false alarms could "cause immense disruptions and panic" and were determined to prevent them, they later wrote in the lab's quarterly magazine.

Sixteen air samplers were positioned at Olympic venues, as well as in downtown Salt Lake City and at the airport. About 5:30 p.m. on Feb. 12, a sample from the airport's C concourse tested positive for anthrax.

Utah Gov. Mike Leavitt was at an Olympic figure skating competition when the state's public safety director, Bob Flowers, called with the news.

"He told me that they had a positive lead on anthrax at the airport," Leavitt recalled. "I asked if they'd retested it. He said they had — not just once, but four times. And each time it tested positive."

The Olympics marked the first major international gathering since the Sept. 11, 2001, airliner hijackings and the deadly anthrax mailings that fall.

"It didn't take a lot of imagination to say, 'This could be the real thing,'" Leavitt said.

But sealing off the airport would disrupt the Olympics. And "the federal government would have stopped transportation all over the country," as it had after Sept. 11, Leavitt said.

Leavitt ordered hazardous-materials crews to stand by at the airport, though without lights and sirens or conspicuous protective gear.

"He was ready to close the airport and call the National Guard," recalled Richard Meyer, then a federal scientist assisting with the detection technology at the Olympics.

After consulting Meyer and other officials, Leavitt decided to wait until a final round of testing was completed. By 9 p.m., when the results were negative, the governor decided not to order any further response.

"It was a false positive," Leavitt said. "But it was a live-fire exercise, I'll tell you that."

Pressing ahead

The implication — that BioWatch could deliver a highly disruptive false alarm — went unheeded.

After the Olympics, Meyer and others who had worked with the air samplers attended meetings at the Pentagon, where Deputy Defense Secretary Paul D. Wolfowitz was building a case for rapidly deploying the technology nationwide.

On Jan. 28, 2003, Bush unveiled BioWatch in his State of the Union address, calling it "the nation's first early-warning network of sensors to detect biological attack."

The next month, a group of science and technology advisors to the Defense Department, including Sidney Drell, the noted Stanford University physicist, expressed surprise that "no formal study has been undertaken" of the Salt Lake City incident. The cause of that false alarm has never been identified.

"It is not realistic to undertake a nationwide, blanket deployment of biosensors," the advisory panel, named the JASON group, concluded.

The warning was ignored in the rush to deploy BioWatch. Administration officials also disbanded a separate working group of prominent scientists with expertise in the pathogens.

That group, established by the Pentagon, had been working to determine how often certain germs appear in nature, members of the panel said in interviews. The answer would be key to avoiding false alarms. The idea was to establish a baseline to distinguish between the natural presence of disease organisms and an attack.

The failure to conduct that work has hobbled the system ever since, particularly in regard to tularemia, which has been involved in nearly all of BioWatch's false alarms.

The bacterium that causes tularemia, or rabbit fever, got its formal name, *Francisella tularensis*, after being found in squirrels in the early 20th century in Central California's Tulare County. About 200 naturally occurring infections in humans are reported every year in the U.S. The disease can be deadly but is readily curable when treated promptly with antibiotics.

Before BioWatch, scientists knew that the tularemia bacterium existed in soil and water. What the

scientists who designed BioWatch did not know — because the fieldwork wasn't done — was that nature is rife with close cousins to it.

The false alarms for tularemia appear to have been triggered by those nonlethal cousins, according to scientists with knowledge of the system.

That BioWatch is sensitive enough to register repeated false alarms but not sensitive enough to reliably detect an attack may seem contradictory. But the two tasks involve different challenges.

Any detection system is likely to encounter naturally occurring organisms like the tularemia bacterium and its cousins. Those encounters have the potential to trigger alerts unless the system can distinguish between benign organisms and harmful ones.

Detecting an attack requires a system that is not only discriminating but also highly sensitive — to guarantee that it won't miss traces of deadly germs that might have been dispersed over a large area.

BioWatch is neither discriminating enough for the one task nor sensitive enough for the other.

The system's inherent flaws and the missing scientific work did not slow its deployment. After Bush's speech, the White House assigned Army Maj. Gen. Stephen Reeves, whose office was responsible for developing defenses against chemical and biological attacks, to get BioWatch up and running.

Over the previous year, Reeves had overseen placement of units similar to the BioWatch samplers throughout the Washington area, including the Pentagon, where several false alarms for anthrax and plague later occurred.

Based on that work and computer modeling of the technology's capabilities, Reeves did not see how BioWatch could reliably detect attacks smaller than, for example, a mass-volume spraying from a crop duster.

Nevertheless, the priority was to carry out Bush's directive, swiftly.

"In the senior-level discussions, the issue of efficacy really wasn't on the table," recalled Reeves, who has since retired from the Army. "It was get it done, tell the president we did good, tell the nation that they're protected.... I thought at the time this was good PR, to calm the nation down. But an effective system? Not a chance."

Why no illness?

It wasn't long before there was a false alarm. Over a three-day period in October 2003, three BioWatch units detected the tularemia bacterium in Houston.

Public health officials were puzzled: The region's hospitals were not reporting anyone sick with the disease.

Dr. Mary desVignes-Kendrick, the city's health director, wanted to question hospital officials in detail to make sure early symptoms of tularemia were not being missed or masked by a flu outbreak. But to desVignes-Kendrick's dismay, Homeland Security officials told her not to tell the doctors and nurses what she was looking for.

"We were hampered by how much we could share on this quote-unquote secret initiative," she said.

After a week, it was clear that the BioWatch alarm was false.

In early 2004, on the eve of the Super Bowl in Houston, BioWatch once again signaled tularemia, desVignes-Kendrick said. The sample was from a location two blocks from Reliant Stadium, where the game was to be played Feb. 1.

DesVignes-Kendrick was skeptical but she and other officials again checked with hospitals before dismissing the warning as another false alarm. The football game was played without interruption.

Nonetheless, three weeks later, Charles E. McQueary, then Homeland Security's undersecretary for science and technology, told a House subcommittee that BioWatch was performing flawlessly.

"I am very pleased with the manner in which BioWatch has worked," he said. "We've had well over half a million samples that have been taken by those sensors. We have yet to have our first false alarm."

Asked in an interview about that statement, McQueary said his denial of any false alarm was based on his belief that the tularemia bacterium had been detected in Houston, albeit not from an attack.

"You can't tell the machine, 'I only want you to detect the one that comes from a terrorist,'" he said.

Whether the Houston alarms involved actual tularemia has never been determined, but researchers later reported the presence of benign relatives of the pathogen in the metropolitan area.

Fear in the capital

In late September 2005, nearly two years after the first cluster of false alarms in Houston, analysis of filters from BioWatch units on and near the National Mall in Washington indicated the presence of tularemia. Tens of thousands of people had visited the Mall that weekend for a book festival and a protest against the Iraq War. Anyone who had been infected would need antibiotics promptly.

For days, officials from the White House and Homeland Security and other federal agencies privately discussed whether to assume the signal was another false alarm and do nothing, or quarantine the Mall and urge those who had been there to get checked for tularemia.

As they waited for further tests, federal officials decided not to alert local healthcare providers to be on the lookout for symptoms, for fear of creating a panic. Homeland Security officials now say findings from lab analysis of the filters did not meet BioWatch standards for declaring an alert.

Six days after the first results, however, CDC scientists broke ranks and began alerting hospitals and clinics. That was little help to visitors who already had left town, however.

"There were 100 people on one conference call — scientists from all over, public health officials — trying to sort out what it meant," recalled Dr. Gregg Pane, director of Washington's health department at the time.

Discussing the incident soon thereafter, Jeffrey Stiefel, then chief BioWatch administrator for Homeland Security, said agency officials were keenly aware that false alarms could damage the system's credibility.

"If I tell a city that they've got a biological event, and it's not a biological event, you no longer trust that system, and the system is useless," Stiefel said on videotape at a biodefense seminar at the National Institutes of Health on Oct. 6, 2005. "It has to have a high reliability."

Ultimately, no one turned up sick with tularemia.

Culture of silence

Homeland Security officials have said little publicly about the false positives. And, citing national security and the classification of information, they have insisted that their local counterparts remain mum as well.

Dr. Jonathan Fielding, Los Angeles County's public health director, whose department has presided over several BioWatch false positives, referred questions to Homeland Security officials.

Dr. Takashi Wada, health officer for Pasadena from 2003 to 2010, was guarded in discussing the BioWatch false positive that occurred on his watch. Wada confirmed that the detection was made, in February 2007, but would not say where in the 23-square-mile city.

"We've been told not to discuss it," he said in an interview.

Dr. Karen Relucio, medical director for the San Mateo County Health Department, acknowledged there was a false positive there in 2008, but declined to elaborate. "I'm not sure it's OK for me to talk about that," said Relucio, who referred further questions to officials in Washington.

In Arizona, officials kept quiet when BioWatch air samplers detected the anthrax pathogen at Super Bowl XLII in February 2008.

Nothing had turned up when technicians checked the enclosed University of Phoenix Stadium before kickoff. But airborne material collected during the first half of the game tested positive for anthrax, said Lt. Col. Jack W. Beasley Jr., chief of the Arizona National Guard's weapons of mass destruction unit.

The Guard rushed some of the genetic material to the state's central BioWatch lab in Phoenix for further testing. Federal and state officials convened a 2 a.m. conference call, only to be told that it was another false alarm.

Although it never made the news, the incident "caused quite a stir," Beasley said.

The director of the state lab, Victor Waddell, said he had been instructed by Homeland Security officials not to discuss the test results. "That's considered national security," he said.

The dreaded call

In the months before the 2008 Democratic National Convention, local, state and federal officials

planned for a worst-case event in Denver, including a biological attack.

Shortly before 9 a.m. on Aug. 28, the convention's final day, that frightening scenario seemed to have come true. That's when Chris Lindley, of the Colorado health department, got the phone call from a colleague, saying BioWatch had detected the tularemia pathogen at the convention site.

Lindley, an epidemiologist who had led a team of Army preventive-medicine specialists in Iraq, had faced crises, but nothing like a bioterrorism attack. Within minutes, chief medical officer Ned Calonge arrived.

Calonge had little faith in BioWatch. A couple of years earlier, the health department had been turned upside down responding to what turned out to be a false alarm for Brucella, a bacterium that primarily affects cattle, on Denver's western outskirts.

"The idea behind BioWatch — that you could put out these ambient air filters and they would provide you with the information to save people exposed to a biological attack — it's a concept that you could only put together in theory," Calonge said in an interview. "It's a poorly conceived strategy for doing early detection that is inherently going to pick up false positives."

Lindley and his team arranged a conference call with scores of officials, including representatives from Homeland Security, the Environmental Protection Agency, the Department of Health and Human Services, the Secret Service and the White House.

None of the BioWatch samplers operated by the state had registered a positive, and no unusual cases of infection appeared to have been diagnosed at area hospitals, Lindley said.

The alert had come from a Secret Service-installed sampler on the grounds of the arena where the convention was taking place. The unit was next to an area filled with satellite trucks broadcasting live news reports on the Democratic gathering. Soon, thousands of conventioneers would be walking from Pepsi Center to nearby Invesco Field to hear Obama's acceptance speech.

Had Lindley and Calonge been asked, they said in interviews, they wouldn't have put the BioWatch unit at this spot, where foot and vehicle traffic could stir up dust and contaminants that might set off a false alarm. As it turned out, a shade tree 12 yards from the sampler had attracted squirrels, potential carriers of tularemia.

The location near the media trailers posed another problem: how to conduct additional tests without setting off a panic.

EPA officials "said on the phone, 'We have a team standing by, ready to go,'" Lindley recalled. But the technicians would have to wear elaborate protective gear.

The sight of emergency responders in moon suits "would have derailed the convention," Calonge said.

On the other hand, sending personnel in street clothes would risk exposing them to the pathogen.

"This was the biggest decision we ever had to make," Lindley said.

When the conference call resumed, Lindley said the state would collect its own samples, without

using conspicuous safety gear. "No one was willing to say, 'That's the right response, Colorado,'" Lindley recalled. "Everybody was frozen. We were on our own."

State workers discreetly gathered samples of soil, water and other items for immediate DNA analysis. No pathogen was found.

At 3 p.m., Lindley told participants in another national conference call that his agency was satisfied there was no threat. "I said: 'We are doing no more sampling. We are closing up this issue,'" Lindley recalled.

Lindley and Calonge, having staked their reputations on not believing BioWatch, were vindicated: Barack Obama gave his acceptance speech on schedule. No one turned up sick with tularemia. And, to their surprise, news of the false alarm never became public.

'An opportunity'

Officials responsible for BioWatch insist that the false alarms, which they refer to as "BioWatch actionable results," or BARs, have been beneficial.

Each incident "has provided local, state and federal government personnel an opportunity to exercise its preparedness plans and coordination activities," three senior Homeland Security BioWatch administrators told a House subcommittee in a statement in July 2008. "These real-world events have been a catalyst for collaboration."

Biologist David M. Engelthaler, who led responses to several BioWatch false positives while serving as Arizona's bioterrorism coordinator, is one of the many public health officials who see it differently.

"A Homeland Security or national security pipe dream," he said, "became our nightmare."

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Document 8

latimes.com/news/nationworld/nation/la-na-biowatch-faulty-assays-20121023,0,6634110.story

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BioWatch technology couldn't detect lethal germs, tests found

Scientists say the U.S. biological defense system relied on kits that were far less able to help detect lethal germs than officials thought.

By David Willman

8:44 AM PDT, October 22, 2012

Washington

WASHINGTON — For two years, the nationwide BioWatch system, intended to protect Americans against a biological attack, operated with defective components that left it unable to detect lethal germs, according to scientists with direct knowledge of the matter.

The federal official who oversaw installation of the components was quietly shifted to a position with no responsibility for BioWatch, and the entire episode was kept out of public view.

The U.S. Department of Homeland Security, which oversees BioWatch, opened an internal investigation, whose status remains confidential.

FULL COVERAGE: BioWatch system plagued by false alarms

In more than 30 cities, BioWatch samplers located atop buildings, in train stations and in other public places suck air through dry filters around the clock. Once a day, the filters are taken to public health laboratories to be analyzed for traces of smallpox, anthrax, plague and other pathogens.

Lab technicians extract genetic material from the filters and then use kits, called assays, to release fluorescent dyes into it. When a laser is shined through the mixture, the dyes are supposed to light up if one of the pathogens targeted by BioWatch is present.

The labs originally used a series of separate assays, each designed to detect a specific germ. In 2007, Homeland Security equipped most of the labs with new kits intended to screen for multiple pathogens at the same time.

The aim was to reduce personnel costs and enable faster detection of a biological attack, and thus a speedier response.

But the new components, called "multiplex" assays, triggered false alarms, a recurring problem with BioWatch since the system was put into operation nationwide in 2003.

After scientists at many of the labs voiced concerns, Homeland Security officials, in consultation with microbiologists from other federal agencies, ordered testing of the new assays.

The tests, conducted in secrecy at the Pacific Northwest National Laboratory in Washington state and the federal Centers for Disease Control and Prevention in Atlanta, found that the kits were unsuitable for BioWatch, scientists familiar with the matter said. They spoke on condition of anonymity, citing the sensitivity of the information.

The multiplex assays could not distinguish between the bacterium that causes tularemia, a potentially deadly condition also known as rabbit fever, and similar but benign organisms called "near neighbors" that are abundant in outdoor environments.

The original assays had exhibited the same problem. But the multiplex assays had an additional shortcoming, scientists said: They were found to be far less sensitive to the presence of actual pathogens than Homeland Security officials had presumed.

In late 2009, Homeland Security officials removed the new assays and returned to using kits that searched for pathogens one at a time.

Peter Boogaard, a Homeland Security spokesman, declined to respond to written questions about the matter. Jeffrey Stiefel, the department official responsible for installing the ill-fated assays, said he was not authorized to comment.

Some of the scientists familiar with BioWatch said the multiplex assays were put into use without adequate testing to validate their effectiveness.

The assays were designed at the CDC and the Lawrence Livermore National Laboratory and were built to Homeland Security's specifications by a private company, the scientists said.

Richard F. Meyer, a microbiologist who helped develop the multiplex assays while at the CDC and later supervised their installation as a contractor for Homeland Security, defended the kits.

Meyer said the original assays "were past their life cycle and in constant need of repair." Data collected by Livermore scientists, he said, "supported the use of the [new] technology."

Meyer acknowledged that he lost his contracting role with Homeland Security because of dissatisfaction over how the multiplex assays performed once installed.

"When you don't agree with those in charge you get pushed aside," he said in an email.

A spokesman for Livermore, Steve Wampler, declined to discuss the lab's role in developing assays for BioWatch.

The failure of the multiplex assays is one in a slew of problems that have beset BioWatch since President George W. Bush unveiled the system during his State of the Union address in January 2003.

Bush said BioWatch would "protect our people and our homeland" against a germ attack by terrorists. In subsequent years, presidential appointees in Homeland Security have repeatedly assured Congress that BioWatch was functioning effectively.

The Los Angeles Times reported in July that BioWatch has been unable to distinguish between dangerous and benign organisms, and that as of 2008, federal agencies had documented 56 false alarms.

In one of those incidents, during the 2008 Democratic National Convention in Denver, BioWatch units signaled the presence of the tularemia bacterium, triggering tense deliberations among local, state and federal officials over what steps should be taken to protect the public.

After follow-up tests found no traces of the germ at the convention site, officials decided not to take emergency measures, and that evening Barack Obama accepted his party's nomination for president on an outdoor stage, as scheduled, before a crowd of more than 80,000 people.

Not once have public health officials had enough confidence in a BioWatch alarm to evacuate an area, dispense antibiotics or take any other emergency action.

After considering the potential disruption from false alarms, federal aviation officials shelved plans to install air-sampling units inside the nation's major airports.

In response to The Times' reporting, congressional Republicans and a senior Democrat have written to Homeland Security Secretary Janet Napolitano seeking documents and explanations. Although Napolitano has not commented publicly, the department's chief medical officer, Dr. Alexander Garza, has staunchly defended BioWatch.

In a statement, Garza said in July that the system had never generated a false alarm. "The detection of commonly occurring environmental agents," he wrote, "is not a 'false positive.'" Asked to elaborate while appearing before a congressional panel Sept. 13, Garza said each detection by BioWatch was "a true positive."

The notion that such events — which Homeland Security calls BioWatch Actionable Results, or BARs — are not false alarms was earlier considered and rejected by a committee of experts appointed by the National Academy of Sciences.

In its report in October 2010, the committee said 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."

FULL COVERAGE: BioWatch system plagued by false alarms

The committee warned that "repeated false alarms may eventually create a sense of skepticism or complacency that could delay or hinder an appropriate response to a true bioterrorism event."

One of the committee members, Northern Arizona University geneticist Paul Keim, said in an interview that the detection of a benign organism could not be considered a "true positive."

"That's why we call them near neighbors," Keim said. "If they cause disease, we call them a pathogen."

Garza, in his recent congressional testimony, said that the existence of the near neighbors had come as a surprise to Homeland Security and that the department was now seeking "more specific assays."

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Document 9

Los Angeles Times

Troubled BioWatch program at a crossroads

After years of concern over false alarms and other problems with the bioterrorism detection system, a House panel wants Homeland Security to explain why an additional $3.1 billion should be spent on it.

December 21, 2012 | By David Willman, Los Angeles Times

WASHINGTON — Year after year, health officials meeting at invitation-only government conferences leveled with one another about Biowatch, the nation's system for detecting deadly pathogens that might be unleashed into the air by terrorists.

They shared stories of repeated false alarms — mistaken warnings of germ attacks from Los Angeles to New York City. Some questioned whether BioWatch worked at all.

They did not publicize their misgivings. Indeed, the sponsor of the conferences, the U.S. Homeland Security Department, insists that BioWatch's operations, in more than 30 cities, be kept mostly secret.

Now, congressional investigators want Homeland Security Secretary Janet Napolitano to open the books on the 9-year-old program and explain why $3.1 billion in additional spending is warranted.

The move by the House Energy and Commerce Committee — spurred by reports in the Los Angeles Times about BioWatch's deficiencies — puts the program at a crossroads.

On one side is mounting evidence that the technology does not work. On the other are companies eager to tap federal contracts, politicians fearful of voting against any program created to fight terrorism, and a top Homeland Security official who says the program is functioning properly.

Government records show that BioWatch signaled attacks more than 100 times when none had occurred. Nor is the system sensitive enough to reliably detect low yet infectious concentrations of such pathogens

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as anthrax, smallpox or plague, according to specialists familiar with test results and computer modeling. Another defect is BioWatch's inability to distinguish between particular pathogens that are genetically similar, but benign.

Lab and field tests found similar problems in the latest technology intended for BioWatch, "Generation 3." The congressional investigators are seeking internal documents illuminating BioWatch's performance, plus the private comments of Napolitano's top science and technology advisor, Dr. Tara O'Toole, who recommended killing Generation 3.

O'Toole's skepticism is shared by Dr. Donald A. Henderson, a renowned epidemiologist who led the global eradication of smallpox. Henderson, a federal anti-terrorism advisor when BioWatch was launched in 2003, says he has yet to see a "scientific justification" for it.

"It has never stood the test of rationality," Henderson said. "This whole concept is just preposterous."

Political ties

But as Napolitano weighs whether to deploy Generation 3 -- at the cost of $3.1 billion over its first five years — the program will not be easy to scale back.

The company in line to install Generation 3, Northrop Grumman Corp., is a major donor to federal campaigns with a broad presence in Washington.

From 2004 to 2012, the company's political action committee gave more than $6 million to congressional candidates, campaign finance records show. Northrop Grumman, a top defense contractor, ranked No. 10 this year among all PAC donors to congressional campaigns.

Northrop Grumman also hired the former head of BioWatch, Dr. Jeffrey W. Runge, as an advisor to assist its pursuit of the Generation 3 contract.

On Sept. 27, Runge told invitees to the Harvard Faculty Club that a survey he designed for what he called "homeland security related professionals" had found support for deploying the new technology, regardless of potential shortcomings.

Rather than wait for more research to refine Generation 3, Runge told the gathering, "the respondents seem to be saying ... 'Deploy the detectors, even if they can't pick up every intentional pathogen or genetic variation, and deal with the problems later.'"

Runge, who provided his prepared remarks to The Times, said Northrop Grumman solicited his advice a few months after he left the government in 2008 and paid him an hourly rate. The consulting arrangement ended in summer 2009, he said.

Runge said the company paid him to explain how the Homeland Security Department "is thinking, how Congress is thinking, about the future of biodetection." Among those he briefed, Runge said, was Northrop Grumman's project manager for Generation 3.

In 2010 and 2011, Northrop Grumman donated a total of $100,000 to the Heritage Foundation, a conservative research group, which, beginning in July, circulated three commentaries supporting federal funding for BioWatch and Generation 3. The donations were disclosed in the group's annual reports.

Steven P. Bucci, a Heritage Foundation senior fellow, wrote on July 11, "BioWatch is far from an 'unnecessary expenditure.' Congress should thus continue to fund the program."

The third Heritage essay, issued Dec. 12 and also written by Bucci, said that although BioWatch was "only marginally effective," Napolitano and President Obama should stay the course. "Cutting funding to this project," he wrote, "leaves us vulnerable in a way that will cripple our future security." Bucci said his writings were his own.

1 | 2 | Next

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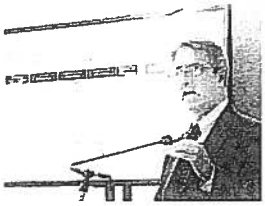

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BioWatch faces congressional hearing this week

A House panel will question officials under oath about the troubled system designed to detect airborne releases of anthrax or other biological weapons.

By David Willman, Los Angeles Times

6:53 PM PDT, June 16, 2013

WASHINGTON — A decade ago, then-Homeland Security Secretary Tom Ridge oversaw the start of BioWatch, the nationwide system designed to detect airborne releases of anthrax or other biological weapons.

In his 2003 State of the Union address, President George W. Bush had announced that BioWatch would "protect our people and our homeland."

Ridge's expectations were not so high.

"Everyone knew it was a primitive, labor-intensive, fairly unsophisticated attempt," Ridge recalled in a recent interview.

On Tuesday, a congressional panel is scheduled to question officials publicly about the program under oath. The House Energy and Commerce Committee began examining BioWatch last year in response to reports in the Los Angeles Times about the system's deficiencies.

In more than 30 U.S. cities, BioWatch units on rooftops and other outdoor locations suck air through dry filters, which are removed every 24 hours and tested at public health laboratories. BioWatch samplers have also been deployed at major spectator events, including the Super Bowl and national political conventions.

The system has been beset by false alarms — nearly 150 to date — some of which triggered tense deliberations over whether to order evacuations, distribute emergency medicines or shut down public venues. In each case, authorities decided to disregard BioWatch.

Confidential government tests and computer modeling have pointed out an even more serious failing: BioWatch could not be relied on to detect an actual germ attack, according to people familiar with its operations.

The federal government has spent more than $1 billion on BioWatch, and the Obama administration has taken preliminary steps to spend billions more on an automated "Generation 3," in which air samples would be continuously analyzed by a "lab in a box" within each unit.

Deployment of Generation 3, however, has stalled. In March, members of the House and Senate appropriations committees — citing "serious concerns" about Generation 3 — said they were declining the Obama administration's request for nearly $40 million for further testing and evaluation of the technology.

The committees reiterated their request that — before a final contract is awarded for the automated system — Homeland Security Secretary Janet Napolitano "certify … that the science used to develop the technology is proven."

Napolitano's subordinates have repeatedly played down or denied flaws in the existing system.

Last year, the department's chief medical officer, Dr. Alexander Garza, a presidential appointee, asserted that BioWatch had never generated a "false positive."

Most of BioWatch's false alarms were triggered by organisms that are genetically similar to lethal pathogens but pose no threat to humans, according to people knowledgeable about the system.

Garza maintained these were not false positives because BioWatch found something in the environment, albeit not the deadly microbes it was intended to detect.

Experts appointed by the National Academy of Sciences have rejected this viewpoint — concluding in a 2010 report that all misidentifications of a pathogen by BioWatch were false positives that "signaled the potential occurrence of a terrorist attack when none has occurred."

The House investigative panel said in a statement last week that BioWatch "has been plagued by false alarms and other failures." According to information newly verified by federal officials, BioWatch has generated at least 149 false alarms.

Garza resigned his post this year to accept a private-sector job. Congressional investigators have questioned others at the Homeland Security Department and the U.S. Centers for Disease Control and Prevention, which administers the nation's stockpile of medicines to treat those exposed to a germ attack.

The investigators have sought to learn why Homeland Security Department officials did not do more to avert false detections of the bacterium tularemia after BioWatch's first false alarms for it in late 2003. Tularemia, also known as rabbit fever, can infect and in rare instances kill humans at relatively low concentrations.

In addition to pressing officials about BioWatch's troubles, investigators have traced how the system functions on a daily basis.

In the event of an intentional release of a pathogen, 36 hours or more could pass before lab testing of BioWatch filters alerted officials to the attack. By then, victims might be crowding emergency rooms, undermining the notion that BioWatch would allow authorities to quickly safeguard a stricken area or dispense medications in time to prevent sickness or death.

BioWatch was installed in 2003 amid widespread fear of biological terrorism — fear stoked, Ridge said, by the fall 2001 anthrax letter attacks, which killed five people.

The FBI ultimately traced those attacks not to a foreign terrorist but to a U.S. government scientist, Bruce E. Ivins, based at the Army's biowarfare research center at Ft. Detrick, Md. Ivins committed suicide in July 2008 after learning that prosecutors were preparing to file charges against him.

Given BioWatch's performance, Ridge said his former department should be wary of sinking more money into it. BioWatch, he said, evokes the Homeland Security Department's $1-billion attempt — now abandoned — to use experimental technology as an invisible fence along the U.S.-Mexico border.

"What [Homeland Security] cannot afford to have if it's going to sustain any credibility with the public is the same kind of thing they did along the border," Ridge said.

david.willman@latimes.com

Document 11

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

July 19, 2012

Dr. Thomas Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. On July 8, 2012, the *Los Angeles Times* reported that the BioWatch air samplers have been plagued by false alarms and other failures. In particular, Federal agencies documented 56 BioWatch false alarms, and State and local health officials have expressed their lack of confidence in BioWatch. Further, according to this same article, officials at the Centers for Disease Control and Prevention told White House aides at a meeting on November 21, 2011, that they would not rush medications to the site of an attack detected by BioWatch unless a BioWatch warning was confirmed by follow-up sampling and analysis.

On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS) , posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

We note that Dr. Garza's representation that BioWatch has never had a false positive result is at odds not only with the incidents reported by the *Los Angeles Times* but also with the observation in an October 2010 report on the BioWatch program by the National Academy of Sciences. The NAS report stated:

> 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.

To assist the Committee in finding out how the BioWatch program is actually performing, and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders, please provide the following by August 2, 2012:

1. All documents since January 1, 2011, relating to the CDC's views about the BioWatch program.

2. List of CDC attendees at the November 21, 2011, meeting with White House aides referenced in the *Los Angeles Times* article, and all documents relating to this meeting.

3. All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.

4. CDC's view of the DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.

5. Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.

An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Document 12

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 16, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Upton:

Thank you for your letter regarding the Department of Homeland Security's (DHS) BioWatch program.

Since the beginning of the BioWatch program, the Centers for Disease Control and Prevention (CDC) has provided assistance as requested by DHS. Specifically, CDC helped establish and staff BioWatch laboratories, develop and validate laboratory methods for detection of targeted biological threat agents, and coordinate the public health response to the possible detection of a biological threat agent. DHS BioWatch laboratories work closely with Laboratory Response Network (LRN) laboratories, which are coordinated by CDC with state and local public health authorities.

As discussed in separate documents being provided to the Committee on Energy and Commerce, the BioWatch program uses a strategy of serial testing and review to assure that a positive laboratory test alone does not trigger an unnecessary major public health response. After determination of a BioWatch Actionable Result (BAR), the jurisdictional authorities collect and review other information for evidence and discuss with federal BioWatch program officials to understand whether the BAR actually represents the detection of release of a biological threat agent or a related organism that may be naturally occurring in the environment or other possible cause. Although the BioWatch program has generated BARs that have been reviewed under this process, none of these has been determined to require a major public health response to date.

In the view of CDC, it is important that BioWatch maintain a robust strategy of testing and review to assure BARs do not lead directly to a conclusion that a threat exists or a high-consequence action is indicated without appropriate confirmation of the existence of a biological threat agent for which the response would be appropriate. CDC and DHS have worked to improve the tests and interpretation of tests results to reduce the number of BARs that do not reflect a true public health threat, and CDC is working with DHS on additional changes that should further improve laboratory testing and related analysis.

Thank you for the opportunity to provide information on the BioWatch program and CDC's work with DHS. Responses to the specific questions posed in your letter are enclosed.

I appreciate your interest in this important program, and look forward to continuing to work with you to improve public health. If you have any questions or require additional information, please have your staff contact Shana Beavin in the CDC Washington Office at (202) 245-0600 or SBeavin@cdc.gov.

Sincerely,

Thomas Frieden

Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Enclosure

Summary of Responses to Information Requests on BioWatch

1. **All documents since January 1, 2011, relating to the CDC's views about the BioWatch program.**

   CDC has not identified any documents relating to the Agency's views on the BioWatch program.

2. **List of CDC attendees at the November 21, 2011, meeting with White House aides referenced in the *Los Angeles Times* article, and all documents relating to this meeting.**

   To clarify, the meeting referenced in the *Los Angeles Times* article took place on November 22, 2011. CDC is providing a list of the CDC attendees at the November 22, 2011, meeting.

3. **All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.**

   Because these documents contain sensitive information, we will work with your staff to ensure your access in an appropriate manner, while seeking limits on further disclosure.

   Upon review, the Committee will notice the documents provided in response to this request are designated sensitive but unclassified (SBU). The justification for the SBU designation is as follows:

   > These documents contain sensitive information about specific devices, techniques, and targets of the LRN assays and should be handled accordingly. CDC requests these documents be safeguarded in a manner that protects them from disclosure, in order to prevent compromise of LRN effectiveness. Review of this material should be limited to those persons whose official duties require it.

4. **CDC's view of DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.**

It is important to clarify what is meant by false positive. At a basic level, a true positive test result is a result that indicates a condition is present when it is in fact present. A fire alarm that goes off in a building when there is a fire in the building is an example of a true positive. A false positive test result is a result that indicates a condition is present when it is NOT in fact present. A fire alarm that goes off in a building when there is NO fire is an example of a false positive. However, a fire alarm might go off due to the presence of smoke or steam, in the absence of a fire, generating what could be considered a false positive, but is both useful and possible to verify before taking further action.

When a test is performed to detect a dangerous but remediable condition, the goal is to detect as many instances of the condition as possible. Testers do not want to miss a remediable situation, e.g., a fire alarm failing to sound despite the presence of a fire. A second (or third) test or other review is used verify the results. This strategy of serial testing and review is used in order to optimize the detection of true positives and minimize the positives that do not warrant high-consequence actions.

The BioWatch program uses a serial testing and review strategy to focus on detecting true positives and minimize the number of positives that might indicate a naturally occurring organism that does not merit a high-consequence action. The BioWatch testing strategy entails at least two separate laboratory tests and multiple reviews:

- The first laboratory test–the BioWatch screening test–is the most sensitive test and regularly produces preliminary positive results to be subjected to further testing.

- The second test–the BioWatch verification test which utilizes assays from the Laboratory Response Network–is more specific as it consists of a suite of assays against multiple segments of DNA. Samples that produce preliminary positive results in the first test undergo this second test, which yields far fewer positive results. Several strategies are used here to determine whether the positive result of the DNA probe is consistent with highly pathogenic organisms or other very similarly related, yet not as pathogenic subspecies of the same organism.

- The BioWatch laboratory director then reviews the results of a positive BioWatch verification test and, as deemed necessary, consults with CDC laboratory scientists and scientists from the BioWatch Program as part of the review. The review is performed to determine whether there is the possibility of a technical or procedural error producing the positive BioWatch verification test. If no technical or procedural error is found, the BioWatch laboratory director then determines that the positive BioWatch verification test constitutes what the BioWatch program calls a BioWatch Actionable Result or BAR. This means that higher level review outside of the laboratory is required.

- After determination of a BAR, the jurisdictional authorities collect and review other information for evidence to understand whether the BAR represents the detection of an organism that is naturally occurring in the environment, release of a biological threat agent, or other possible causes. This additional investigation may entail the review of laboratory, epidemiological, law enforcement, or intelligence information, and it may entail the collection of additional samples for laboratory analysis. The BioWatch program expects the jurisdictional authorities to review and discuss their findings on a national conference call

with federal BioWatch Program officials, and officials from DHS and other federal agencies that support the BioWatch Program before taking any high-consequence action.

Since its inception in 2003, the BioWatch program has experienced a number of BARs which have been attributed to environmental agents. These infrequent results are expected in testing for any rare condition. Although initial positive BARs do occur, it is important to note that BioWatch has implemented an overall response strategy to ensure that a single piece of data, such as a BAR, does not lead directly to a high-consequence action.

When DHS states that the BioWatch program has not produced false positive results, CDC's understanding is that they are looking at the overall outcome of the entire testing and review strategy (Steps 1-4 outlined above) rather than just the occurrence of a BAR in isolation from other pertinent information. And that a positive PCR test is indicating the detection of some substance of a targeted microorganism that may also occur naturally in the environment, but not be the act of bioterrorism.

Investigations of BARs have led to modifications of BioWatch testing that have substantially reduced the rate of occurrence of BARs in BioWatch testing over time. In 2012 to date, BioWatch has experienced only five BARs. Further improvements are underway in BioWatch assays that should further enable the BioWatch Program to distinguish between non-disease and disease causing strains of organisms that are naturally occurring in the environment.

5. **Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.**

- Improvements to laboratory components of the BioWatch program were made as a result of consultations between CDC and DHS: In December 2009, BioWatch adopted a procedural change for *Y. pestis* in order to reduce the possibility of positive BAR for *Y. pestis*

- In March 2010, BioWatch implemented a comprehensive quality assurance program in order to provide standardized, on-going, external evaluation of laboratory performance. It focuses on six major areas of quality assurance: (1) document control; (2) data reporting; (3) procedures and equipment; (4) training, qualification and competency; (5) procurement; and (6) corrective action/root cause analysis.

- In August 2011, BioWatch reduced the real-time polymerase chain reaction cycle threshold (Ct) cut-off for both the BioWatch screening and LRN verification assays. The change was undertaken based on a systematic review of over 4,000 reactive screening results that required verification testing. Review of data after this change was implemented, comparing results from August 2010–July 2011 to those from August 2011–May 2012, revealed a 30 percent reduction in the number of reactive results observed for *F. tularensis*. This move to a lower Ct value is consistent with best practices from other biological environmental detection systems including the Department of Defense.

- The BioWatch program is preparing to field and CDC is developing more specific nucleic acid signatures for *F. tularensis*, *Y. pestis*, and *Variola* based on new knowledge about cross-reactivities of the current signatures with closely-related but not highly pathogenic organisms. Once the new signatures have been validated, they will be deployed into the

BioWatch program. This should further reduce the frequency of BARs, especially for *F. tularensis*.

- The BioWatch program recently began using an assay from the U.S. Department of Defense Critical Reagents Program for its initial screening test rather than LRN assays. This change eliminated duplication of signatures in the screening and verification assays and increased the specificity of the serial testing. This strategy was adopted in February 2012 and is now operational.

Over the course of the BioWatch program, CDC and DHS have collaborated to identify areas for enhancements to laboratory components of the BioWatch program. Together, both agencies work to implement necessary change. CDC will continue to work with DHS to make improvements as opportunities for advancement are identified.

Document 13

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

July 19, 2012

The Honorable Janet Napolitano
Secretary
Department of Homeland Security
Washington, D.C. 20528

Dear Secretary Napolitano:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. On July 8, 2012, the *Los Angeles Times* reported that the BioWatch air samplers have been plagued by false alarms and other failures. In particular, Federal agencies documented 56 BioWatch false alarms, and State and local health officials have expressed their lack of confidence in BioWatch.

On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

We note that Dr. Garza's representation that BioWatch has never had a false positive result is at odds not only with the incidents reported by the *Los Angeles Times* but also with the observation in an October 2010 report on the BioWatch program by the National Academy of Sciences (NAS). The NAS report stated:

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.

To assist the Committee in finding out how the BioWatch program is actually performing, and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders, please provide the following by August 2, 2012:

1. All documents (including emails, meeting minutes, slides) since January 1, 2008, in the possession of Dr. Tara O'Toole, Dr. Alexander Garza, Dr. Michael Walter, Dr. Jeff Stiefel, and/or Dr. Segran Pollai relating to BioWatch or any generation of the BioWatch program.

2. All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.

3. Evidence for the DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.

4. Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.

An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 14

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

November 13, 2012

Dr. Thomas Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system.

On July 19, 2012, we wrote to you requesting information and documents to determine how the BioWatch program is performing and whether it is meeting public protection goals. We expressed particular interest in a news report indicating that officials at the Centers for Disease Control and Prevention (CDC) told White House aides at a meeting on November 21, 2011, that they would not rush medications to the site of an attack detected by BioWatch unless a BioWatch warning was confirmed by follow-up sampling and analysis. To date, CDC has provided insufficient responses to our July 19, 2012, inquiry. Moreover, in the intervening time additional details have come to light regarding program failures.

The Los Angeles Times reported on October 23, 2012, that the BioWatch system operated with defective components that left it unable to detect deadly pathogens for a two-year period, according to scientists with direct knowledge on the matter. The article raises further questions about the BioWatch program, in addition to the ones raised in our July 19, 2012, letter.

To assist the Committee in its examination of these additional issues, please provide the following by November 26, 2012:

1. All documents relating to the tests conducted by CDC that found multiplex assays unsuitable for BioWatch.

2. All documents dated since January 1, 2009, in the possession of Dr. Toby Merlin and/or Dr. Stephen Morse relating to BioWatch.

In addition to the above requested information, we seek your cooperation in responding to the July 19, 2012, request letter. The response from CDC to date has been inadequate, highlighting, at minimum, a lack of coordination and communication among agencies, and making clear that CDC or Department of Health and Human Services (HHS) is withholding responsive documents.

In the more than three months since our initial request, CDC has produced only two pages of test results. CDC staff advised Committee staff that documents have been submitted to the Department of Health and Human Services for clearance. However, HHS told Committee staff there are no documents from CDC in clearance, and that CDC advised them there are no responsive documents. CDC persisted in telling Committee staff that there are documents in clearance even after being advised that HHS denied that was the case. CDC has also claimed for weeks that a letter response is also in the clearance process at HHS.

On October 11, 2012, CDC provided a phone briefing for Committee staff with Dr. Toby Merlin. Dr. Merlin spent considerable time briefing Committee staff in cooperation with our efforts. In the course of that briefing, Dr. Merlin provided information demonstrating that CDC is in possession of responsive documents that have not been provided to the Committee. For example, Dr. Merlin acknowledged problems with the BioWatch assays cross-reacting with benign organisms in the environment, so-called near neighbors to the pathogen of concern, especially in the context of the Francisella tularensis test results. In response to a question from Committee staff, Dr. Merlin said he would call such a test result detecting a near neighbor a "false positive." This statement was responsive to request number 4 from the July 19, 2012, letter, one of several questions to which CDC has not provided an adequate written response. We urge CDC to resolve its internal difficulties with the Department and cooperate with the Committee's investigation as CDC has done on other occasions.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 15

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 25, 2013

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Upton:

Thank you for your letter and for the opportunity to provide further clarification and documents regarding the Department of Homeland Security's (DHS) BioWatch program and development of BioWatch multiplex assays.

As you are aware, the Centers for Disease Control and Prevention (CDC) provided assistance to the BioWatch program as requested by DHS. Specifically, CDC helped establish and staff BioWatch laboratories, develop and validate laboratory methods for detection of targeted biological threat agents, and coordinate the public health response to the possible detection of a biological threat agent. DHS BioWatch laboratories work closely with Laboratory Response Network (LRN) laboratories, which are coordinated by CDC with state and local public health authorities.

In your recent letter, you mention an October 22, 2012, *Los Angeles Times* article that raised concerns about the development and deployment of BioWatch multiplex assays. Unfortunately, that article gave an incorrect impression of CDC's involvement in a complex process. In 2006, CDC was asked by DHS to recommend an alternative laboratory technology for detection of biothreat agents. CDC recommended DHS consider use of multiplex assays, and provided technical expertise and detailed a scientist to work with DHS in the development of the multiplex assays technology for the BioWatch program. In 2007, after DHS and the Lawrence Livermore Laboratory (LLNL) completed work on development of these assays, DHS determined to move forward with initial deployment of the multiplex assays into the field. CDC did not, however, formally review or approve the performance of the assays before DHS began to deploy them in November 2007. In 2008, when performance data was shared with the CDC, CDC informed DHS of concerns about the assays that eventually led to their discontinuation by DHS. DHS subsequently established a BioWatch Technical Advisory Committee (BTAC) that included experts from several agencies, including CDC, to evaluate the multiplex assays. The BTAC ultimately determined that the previously deployed singleplex Real-Time PCR assays were more appropriate.

Per your letter's request, we are currently in the process of providing documents to the Committee, and we will continue to keep you and your staff updated on the status of this process.

Thank you again for your letter and for your interest in this important program. We look forward to continuing to work with you to improve public health. If you have any questions or require additional information, please have your staff contact Shana Beavin in the CDC Washington Office at (202) 245-0600 or SBeavin@cdc.gov.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Document 16

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

November 13, 2012

The Honorable Janet Napolitano
Secretary
Department of Homeland Security
Washington, D.C. 20528

Dear Secretary Napolitano:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system.

On July 19, 2012, we wrote to you requesting information and documents to determine how the BioWatch program is performing and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders. Our initial inquiry came, in part, in response to news accounts of false alarms and other system failures. To date, the Department of Homeland Security (DHS or "Department")) has provided insufficient responses to our July 19, 2012, inquiry. Moreover, in the intervening time additional details have come to light regarding program failures.

The Los Angeles Times reported on October 23, 2012, that the BioWatch system operated with defective components that left it unable to detect deadly pathogens for a two-year period, according to scientists with direct knowledge on the matter.

To assist the Committee in its examination of these additional issues, please provide the following by November 26, 2012:

1. Please confirm whether the BioWatch system operated with defective components. If so, please provide the date(s) DHS learned that the components were defective. If not, please provide the basis for DHS concluding that the components were not defective, and supporting documentation.

2. A written explanation for why the Federal official who oversaw installation of the components was removed from his position of responsibility in the Biowatch program, and the date he was removed.

3. An explanation of the basis for the DHS decision to deploy the multiplex assays, and the supporting documentation and data for this basis, particularly test results validating their effectiveness prior to deployment.

4. An explanation for the DHS withdrawal of the multiplex assays, and the documentation and data supporting the basis for the withdrawal.

5. A list of the State and local partners of the BioWatch program, and the dates each of these partners were notified by DHS about the results of tests conducted at the Pacific Northwest National Laboratory and the Centers for Disease Control and Prevention that found that the multiplex assays were unsuitable for BioWatch.

6. A statement detailing the sensitivity of the multiplex assays for detecting actual pathogens, and supporting documentation and data for the statement.

In addition to the above requested information, we seek your cooperation in obtaining a response to the July 19, 2012, request letter. The response from DHS to date has been inadequate, raising serious questions about the Department's willingness to cooperate with efforts to ensure the success of the BioWatch program and transparency about its potential failures. Although DHS raised concerns with our inquiry and the Committee has attempted to accommodate, the Department continues to withhold key documents more than three months after our initial request.

When DHS expressed concern about the potential scope of the document request, Committee staff proposed initial production of a small batch of documents from five DHS officials named in the request letter. DHS agreed, but has so far produced documents from only three of the five DHS officials, along with a single document from a fourth.

DHS justified the non-production of documents from the remaining two officials, Undersecretary Tara O'Toole and Dr. Segran Pillai, because the Science and Technology Directorate was involved with the future of the Biowatch program and not the past performance of Biowatch, which DHS considered to be the focus of the Committee's investigation. DHS instead permitted officials from the directorates of Health Affairs and Science and Technology (but not Dr. O'Toole or Dr. Pillai) to brief Committee staff last month.

After that briefing, DHS agreed to provide the documents from the remaining two officials as previously agreed to with Committee staff. More than a week later, and only in response to an inquiry from Committee staff, DHS staff notified the Committee that the Department would not provide the documents because of ongoing litigation between legislative and executive branches regarding congressional requests for internal, deliberative documents. This latest rationale for refusing to turn over the requested documents is inconsistent

with DHS's previous document productions in this matter and is an insufficient reason for non-compliance with our requests.

We urge DHS to complete its agreement with Committee staff and provide the batch of documents from the remaining DHS officials, Dr. Tara O'Toole and Dr. Segran Pillai, by no later than November 26, 2012.

An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 17

Office of Legislative Affairs
U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

January 25, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton:

Thank you for your November 13, 2012 letter regarding the BioWatch program. I appreciate the opportunity to respond to your questions and provide a more comprehensive understanding of the BioWatch Program and its technology.

The Department of Homeland Security (DHS) is committed to utilizing the best technology available to allow the Nation to respond as quickly as possible to a biological threat and deliver life-saving medical countermeasures. BioWatch provides environmental biodetection, by utilizing a system of collectors whose filters are manually retrieved for subsequent analysis by laboratory technicians, and maintains an open dialogue with its federal, state, and local partners.

In 2006, as a part of the effort to increase the system's ability to accomplish its mission effectively and efficiently, DHS asked the Centers for Disease Control and Prevention (CDC) to recommend an alternative laboratory technology for detection of biothreat agents that would enable the BioWatch program to provide timely detection of these agents at reduced operating costs. CDC recommended that the BioWatch program evaluate use of multiplex assays[1], and in January 2007, CDC detailed a scientist to work with DHS on this technology.

Later in 2007, based on work conducted at DHS and the Lawrence Livermore National Laboratory (LLNL), DHS moved forward with initial deployment of the multiplex assays into the field, and DHS began a limited transition from single-plex assays. The timetable of this limited transition is given on the enclosed document.

In 2008, CDC raised concerns about potential limitations in the performance of the multiplex assay when performance data was shared with them, and DHS's Office of Health Affairs (OHA) requested that the Science and Technology Directorate (S&T) conduct an evaluation of the multiplex assays that were developed by LLNL and deployed in the BioWatch

[1] Multiplex assays can detect several different organisms in a single sample, and multiplex assays are generally more efficient, as they require less time and reagents.

Program. S&T established a BioWatch Technical Advisory Committee (BTAC) that encompassed technical experts from half a dozen agencies and sub-agencies, with the goal of determining the robustness of the multiplex assays for use in the BioWatch program to meet the intended use and application. BTAC members evaluated reports and data generated by LLNL and the Pacific Northwest National Laboratory (PNNL) and determined that the previously deployed single-plex real-time polymerase chain reaction (PCR) assays were more appropriate.

As a result of these findings, the BTAC recommended to OHA on July 16, 2009 that BioWatch revert back to single-plex real-time PCR assays for sample analysis. BioWatch laboratories transitioned back to the single-plex real-time PCR assays by August 2009. State and local partners of the BioWatch program were informed of the PNNL study on January 19, 2010, in New York City. A list of state and local BioWatch jurisdictions is enclosed with this letter, as is a chart with the dates of the assay transition back to single-plex real-time PCR assays.

Your letter also references a media report that the BioWatch system operated with defective components for a two-year period. The BioWatch Generation 1/2 unit, also known as a portable sample unit (PSU), is an aerosol collector whose filters are manually retrieved for subsequent analysis in a laboratory. At no time did DHS determine that the PSUs were operating with defective components, nor did DHS receive any reports that the PSUs were malfunctioning due to defective components. While we do not know the reason for this assertion in the media report, it may be that the discussion of "defective components" was a reference to the concerns regarding the BioPlex assays.

With regard to the Department's production of documents responsive to your July 19, 2012 letter, we have produced approximately 3,000 pages of documents and are currently preparing more documents for you.

Thank you again for your letter. I hope this response addresses your concerns. DHS welcomes your interest in this important matter and looks forward to continuing to work with you. Should you have additional questions, please do not hesitate to contact me at (202) 447-5890

Respectfully,

Nelson Peacock
Assistant Secretary for Legislative Affairs

Enclosures

cc: The Honorable Cliff Stearns, c/o Clerk of the House
The Honorable Henry Waxman, Ranking Member, Committee on Energy and Commerce
The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigation

Document 18

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

January 31, 2013

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20221

Dear Secretary Sebelius:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce continues its investigation of the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. This letter hereby reauthorizes the request sent to the Centers for Disease Control and Prevention (CDC) on November 13, 2012.

It is our understanding that the CDC document production in response to the November 13, 2012, document request letter is still under review at the Department of Health and Human Services (HHS). There has been no production of any documents from HHS, although the Department of Homeland Security (DHS) has made substantial document production to the Committee in response to our BioWatch-related document request made on November 13, 2012. Prompt production of these documents from HHS is needed to help the Committee proceed with this inquiry with the benefit of the CDC's expertise and knowledge in this area.

We note that a December 22, 2012, article in the *Los Angeles Times* continued to raise concerns about BioWatch, especially the question of how best to protect public health. For example, the *Los Angeles Times* reported that Dr. Arthur L. Kellerman, a physician and public health researcher at Rand Corporation, who studied BioWatch as a member of a National Academy of Sciences committee, said it "has generated nothing but false alarms." Dr. Kellerman and other specialists, according to the *Los Angeles Times*, said the money spent on BioWatch could have paid for training and equipment to help medical professionals more quickly diagnose a patient exposed to an attack. These experts are concerned that the many false alarms invite complacency.

Because of the CDC's role in BioWatch and the important public health protection issues raised, we urge you to expedite this document production so we can work with you and your Department more effectively on improving protection against the threat of bioterrorism.

To assist the Committee in its examination of the issues raised in the November 13, 2012, letter, please provide the following by February 14, 2013:

1. All documents relating to the tests conducted by the CDC that found multiplex assays unsuitable for BioWatch.

2. All documents dated since January 1, 2009, in the possession of Dr. Toby Merlin and/or Dr. Stephen Morse relating to BioWatch.

If the Department cannot provide complete document production by the requested deadline, we request that the Department provide evidence of cooperation with this request before February 14, 2013. Such evidence of cooperation must include a significant partial production, detailed information on how the production is being managed (number of FTEs handling, number of hours devoted to processing the request, number of pages being processed, internal emails substantiating the date CDC provided the documents to HHS), and a timetable of production.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Thomas Frieden, M.D., Director, CDC

The Honorable Jim Esquea, Assistant Secretary for Legislation, HHS

The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 19

Slobodin, Alan

From: Mann, Melissa <melissa.mann@HQ.DHS.GOV>
Sent: Monday, June 10, 2013 4:22 PM
To: Slobodin, Alan; Meyer, Jonathan; Chieco, Gena
Cc: Anderson, Carl; Havens, Brittany; Cohen, Brian; Gopal, Kiren
Subject: RE: BioWatch production #13

Alan, since October 2003 there have been 149 BARs.

-----Original Message-----
From: Slobodin, Alan [mailto:Alan.Slobodin@mail.house.gov]
Sent: Monday, June 10, 2013 3:03 PM
To: Meyer, Jonathan; Chieco, Gena; Mann, Melissa
Cc: Anderson, Carl; Havens, Brittany; Cohen, Brian; Gopal, Kiren
Subject: FW: BioWatch production #13

This one may have been lost in the shuffle with folks out on vacation, etc., at the time of the request. Does DHS have an answer? Thanks.

-----Original Message-----
From: Slobodin, Alan
Sent: Tuesday, May 28, 2013 2:03 PM
To: 'Mann, Melissa'
Cc: Meyer, Jonathan; Chieco, Gena; Sessa, Eric; Gross-Davis, Leslie; Gopal, Kiren
Subject: RE: BioWatch production #13

How many BARS have occurred in the BioWatch program? Thanks.

-----Original Message-----
From: Mann, Melissa [mailto:melissa.mann@HQ.DHS.GOV]
Sent: Thursday, May 23, 2013 5:35 PM
To: Slobodin, Alan; Gopal, Kiren
Cc: Meyer, Jonathan; Chieco, Gena; Sessa, Eric; Gross-Davis, Leslie
Subject: BioWatch production #13

Alan, Kiren - Another production coming your way, est. delivery time noon tomorrow. If you have a conflict let us know. Thanks,

Document 20

Slobodin, Alan

From: Mann, Melissa <melissa.mann@HQ.DHS.GOV>
Sent: Friday, June 14, 2013 11:13 AM
To: Gopal, Kiren
Cc: Cohen, Brian; Havens, Brittany; Anderson, Carl; Slobodin, Alan; Meyer, Jonathan; Chieco, Gena
Subject: jurisdictions and follow up
Attachments: BioWatch Jurisdictions.pdf

Kiren, per your request:

1. List of jurisdictions attached
2. Breakdown of BARS by year:
   - 2003: 8
   - 2004: 19
   - 2005: 4
   - 2006: 9
   - 2007: 31
   - 2008: 16
   - 2009: 20
   - 2010: 23
   - 2011: 14
   - 2012: 5

Document 21

[redacted]

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Tuesday, October 09, 2012 12:04 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: RE: Jasmine, Please remind me of the total number of BARS since BioWatch inception?

Categories: Red Category

We now have 149 BARS

Jasmine
LRN Program Office

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 09, 2012 10:18 AM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: Jasmine, Please remind me of the total number of BARS since BioWatch inception?

I'm apparently going to have to talk to a Congressional staffer on Thursday, and they anticipate this question.
Thanks,
Toby

Document 22

Slobodin, Alan

From: [redacted]
Sent: Wednesday, May 29, 2013 1:12 PM
To: Slobodin, Alan
Cc: [redacted] Gopal, Kiren; [redacted]
Subject: RE: BioWatch

Hi Alan-

Sorry for the delay in responding. Dr. Merlin was out of the office. He is available on June 18th for the hearing. Do you have any additional information on the hearing that you can share with us?

Here is the information you requested below.

Total BARS to date=149
Total for 2012 = 5
Total for 2013 to date = 0

Thanks,

[redacted]

From: [redacted]
Sent: Tuesday, May 28, 2013 4:08 PM
To: 'Slobodin, Alan'
Cc: [redacted] Gopal, Kiren; [redacted]
Subject: RE: BioWatch

Hi Alan

I will go back and check on the information requested. Dr. Merlin is out of the office today so we will check his calendar let you know about the 6/18 date.

Thanks,

[redacted]

From: Slobodin, Alan [mailto:Alan.Slobodin@mail.house.gov]
Sent: Tuesday, May 28, 2013 2:04 PM
To: [redacted]
Cc: [redacted] Gopal, Kiren; [redacted]
Subject: RE: BioWatch

Shana, according to CDC, how many BARs have occurred in the BioWatch program? Thanks.

From: [redacted]
Sent: Friday, May 17, 2013 4:53 PM
To: Slobodin, Alan
Cc: [redacted] Gopal, Kiren; [redacted]
Subject: RE: BioWatch

Hi Alan-

Thanks for your email and we will be in touch regarding next steps.

Thank you and have a nice weekend.

[redacted]

From: Slobodin, Alan [mailto:Alan.Slobodin@mail.house.gov]
Sent: Friday, May 17, 2013 1:00 PM
To: [redacted]
Cc: [redacted] Gopal, Kiren
Subject: BioWatch

I've been given the green light to proceed with a hearing on BioWatch that would be held June 12th. I wanted to give you a heads-up that we will be inviting CDC to testify at this hearing, and wanted to ensure an appropriate CDC witness is available to testify. Thanks.

Document 23

[redacted]

From: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thursday, October 13, 2011 10:07 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
Please share with Beth, that there were three process to support standards for biodetection out of DHS S&T.

1. Public Safety Actionable Assay which was intended to support the evaluation of Field Screening Assays manufactured of commercial companies for First Responder Use. The conops associated with this effort is directly attributed to saftey related actions such as evacuation of buildings, decon of potentially exposed individuals, expediting the transfer of sample to the LRN for confirmation etc. In addition to the above regardless of whether a sample is positive or negative, the sample is still forwarded to a LRN lab for secondary testing to eliminated False Positives and False Negatives

2. Federal Standards for Assay Performance and Equivalency. This was specifically design to support and fulfill the National Biomonitoring Program and under a MOU signed among Asst Sec. from DoJ, DoD, HHS, DHS and USPS which all had a biomonitoring program at that time. The task was delegated to DHS S&T to implement a process for for establishing Assay performance Equivalence among the programs so the federal partners recognize the credibility to support the initiation public health response in a timely manner. This is the effort Garza is referring to. We actually briefed CDC leadership about a year ago during Lisa Rotz time to Ali, Beth, Dan and others and they already signed off on it just like all the other agencies except of OHA and USPS at the current time. The issues with USPS is being dealt by NSS because they just don't have the money to continue and operate the BDS and they are the process of reevaluating the program (please hold this information close. This is not for sharing at the current time). With regards to OHA, we have forwarded all the versions multiple time over the past several years and they keep ignoring and not truly engaging in the effort although we have tried many time. They have come up with multiple excuses over the years and questions which we had address all of them. So, I don't know what their true concerns are, but for a high profile program like BioWatch, it will be in their best interest to put their assays and system through a robust process to ensure they function and operate at an optimal level to support the Nation with an early warning of a biological attack. Several months ago Mike Farrell from the BRRAT lab evaluated the Assay Chemistry being used by the NG Gen 3 system at the request of OHA BioWatch program. His finding were similar to our findings when we did the evaluation of Gen 2.5 the Bioplex assays. That is the assay chemistry is fundamentally flawed and have to be addressed immediately and had shared this with OHA. As per Mike, they ignored is and upon Mike revisiting this issue, they shared with him that they will fix it after procurement which is highly troubling (please check with Mike for specifics). I don't know if OHA BioWatch is worried that if they were to put the assays through the FSAPE process they might failed and is trying to bypass it. They have insisted to us that the PSAA process is a better process and as such want to put their systems through that process which was intended for Public Safety Actions. My thoughts on this is that they can go through the process and if they get a positive signal, they can retrieve the sample from the detectors and take to the closest LRN Lab for confirmation, however if they were to miss a detection, there is no mechanism to capture it (referring to false negative result) simply because the negative samples will not be retrieved and taken to a LRN Lab for secondary testing.

3. Public Health Actionable Assays. This is specifically to support the assay development, evaluation, validation and certification of the assays deployed and employed through the CDC LRN. This has nothing to do with OHA or BioWatch. This is strictly related to the LRN assays to support National BioPrepardness and Defense and Public Health Surveillance mission. These assays are intended to be highly robust for use in a LRN laboratory to evaluate environmental samples that comes to the lab, support epi investigation associated with a bioterrorism event as well as clinical sample to support medical and clinical intervention. We worked with many folks form CDC all the way from LRN TRC director, LRN Manager, Environmental Microbiology Director, SME Lab Directors, Branch Chiefs and Division Directors for the input and contribution to the PHAA plan simply because we wanted to ensure that the assays deployed and employed through the CDC LRN are highly robust to support the mission.

Hope this helps and I am on travel to the West Coast and will return back to the office next week. If you would like to chat, please let me know and I can give you a call at you convenience. Take care.

Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thu Oct 13 08:53:21 2011
Subject: RE: Signatures on current PHAA document

Pillai,

I'm going to get the specifics from Beth again, because I want to be sure I get them right, and I will send them along later. I think they primarily have to do with the impression that the Biowatch program and Gen-3 will have to meet PHAA standards and be approved by PHAAC as a condition of deployment. But, let me see exactly what Beth says.
Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 8:31 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
Can you please share with me the concerns raised by Alex to Beth pertaining to the PHAA? Thanks and appreciate your help and assistance on this. Take care.
Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Wed Oct 12 11:42:41 2011
Subject: Signatures on current PHAA document

Pillai,

I met with Beth Bell and other members of our Center leadership yesterday, and we discussed the requested signatures on the PHAA document. Beth tells me that she recently met with Alex Garza from DHS-OHA where he explicitly raised his concerns about PHAA. We seem to be at a juncture where DHS-S&T and DHS-OHA need to resolve their internal disagreements over PHAA and present us with a PHAA document for CDC signature that has cleared stakeholders at DHS. Personally I believe there is a critical need for standards and the differences between DHS-OHA and DHS S&T are resolvable.

I am willing to discuss and help in any way you like.

Thanks,
Toby

Document 24

From: [redacted]
To: Walter, Michael
Subject: Re: FYI some good news, I think.
Date: Thursday, December 08, 2011 7:21:51 AM

Thanks Mike.

Would you like a meeting with FPS HQ to get a more consistent approach to providing biodetection in their facilities nationally? I know some of their senior leadership.

[redacted]
Sent from BB

From: Walter, Michael
To: Garza, Alexander <Alexander.Garza@dhs.gov>; [redacted]
Cc: [redacted]
Sent: Thu Dec 08 07:14:44 2011
Subject: FYI some good news, I think.

Dr. Garza/Bob... things you should be aware of since we do not have a staff meeting

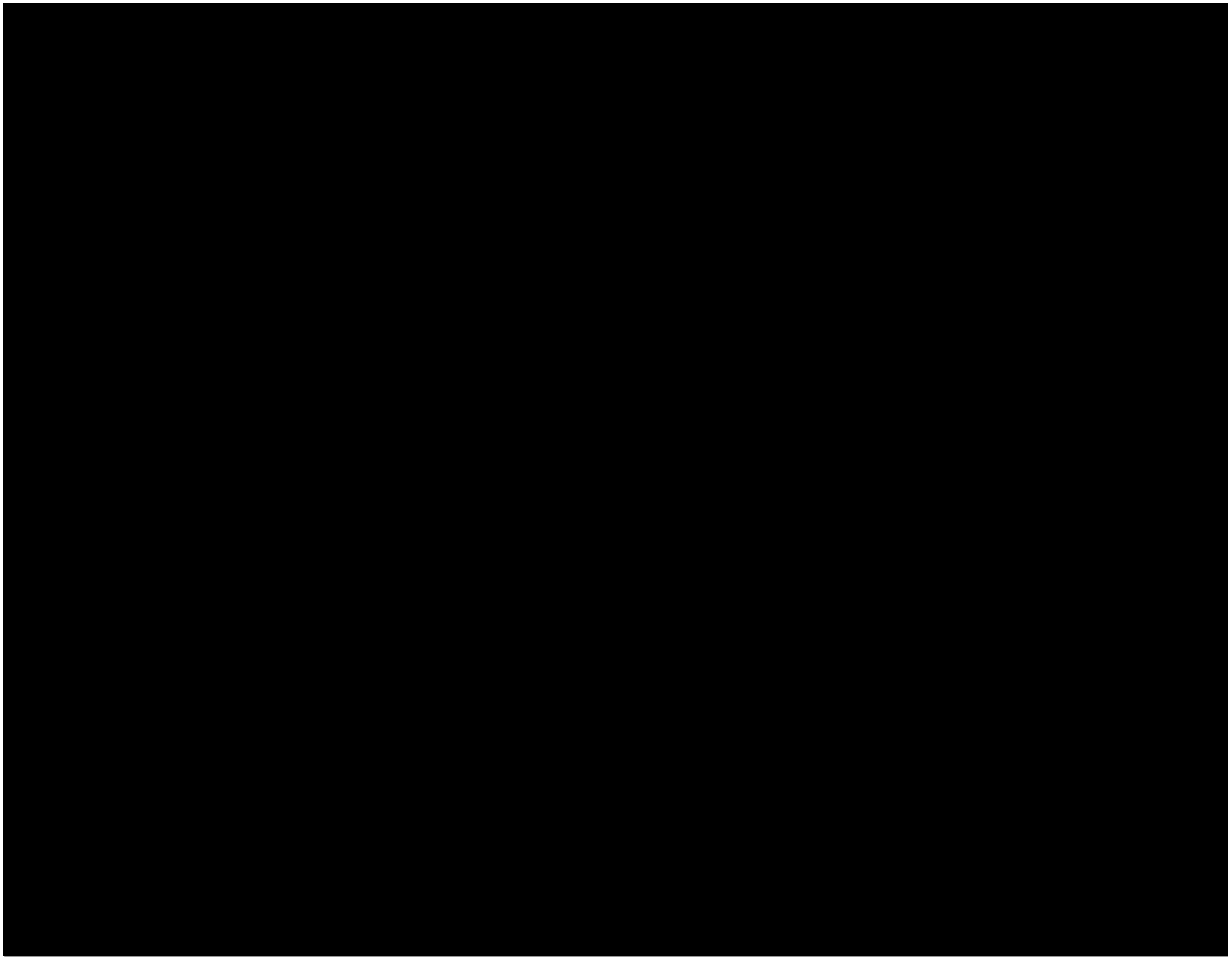
1. We met with the USSS and EPA and have an agreement that EPA will provide Phase 1 and 2 sample support. EPA understands that they will change filters at NSSEs only if we request them to. They will also do the sampling plans for our and any systems that the USSS will put out....good meeting.
2. Had a conference call with the [redacted]. They are installing a commercial Bio-trigger (IBAC from ICXT) and wanted my advice on how to coordinate with the city and BioWatch regarding sample analysis and response. I recommended a meeting between Public Health and NYPD and at my suggestion they are now leaning towards deployment of a [redacted]. They would also like to discuss BioWatch [redacted]. I will meet with FPS in the next couple of weeks or early January, but will discuss the meeting with [redacted] today while I am up there. Meeting was facilitated by S&T.
3. Got word that JPEO has removed funding from all future biodetection programs with the exception of the tactical detection system. This includes shutting down their standoff program. This makes BioWatch the only game in town.

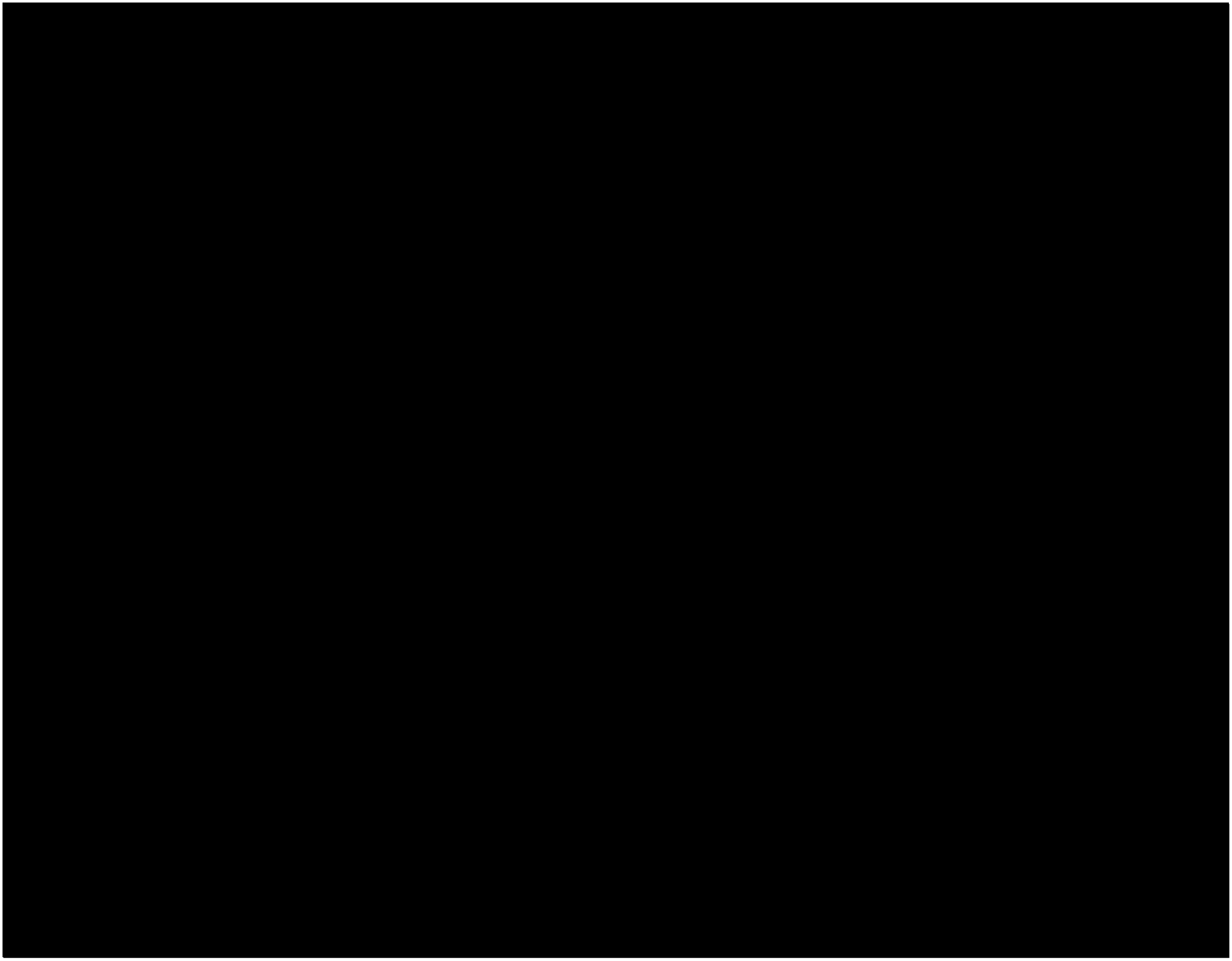
FYI in case it comes up.

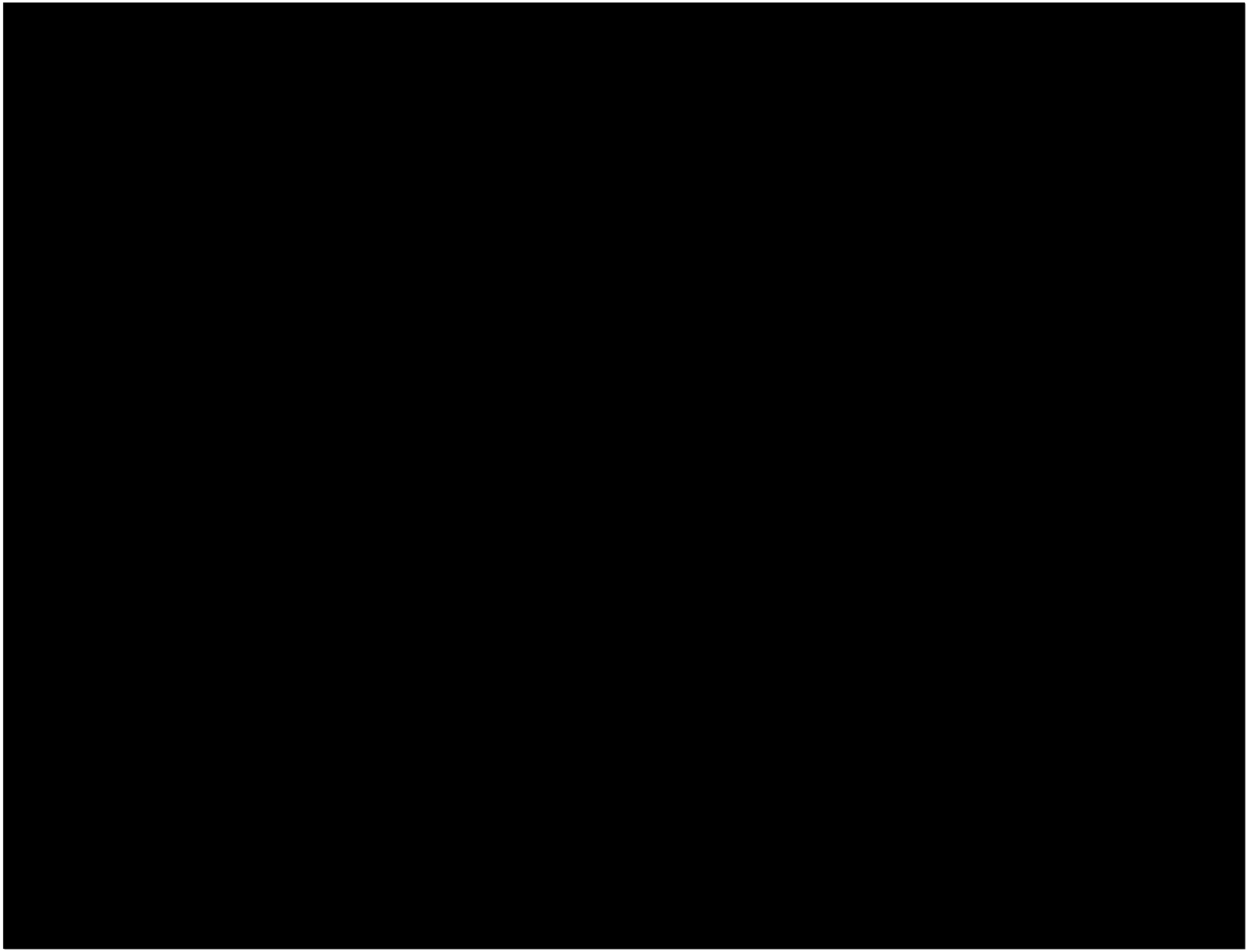
Mike

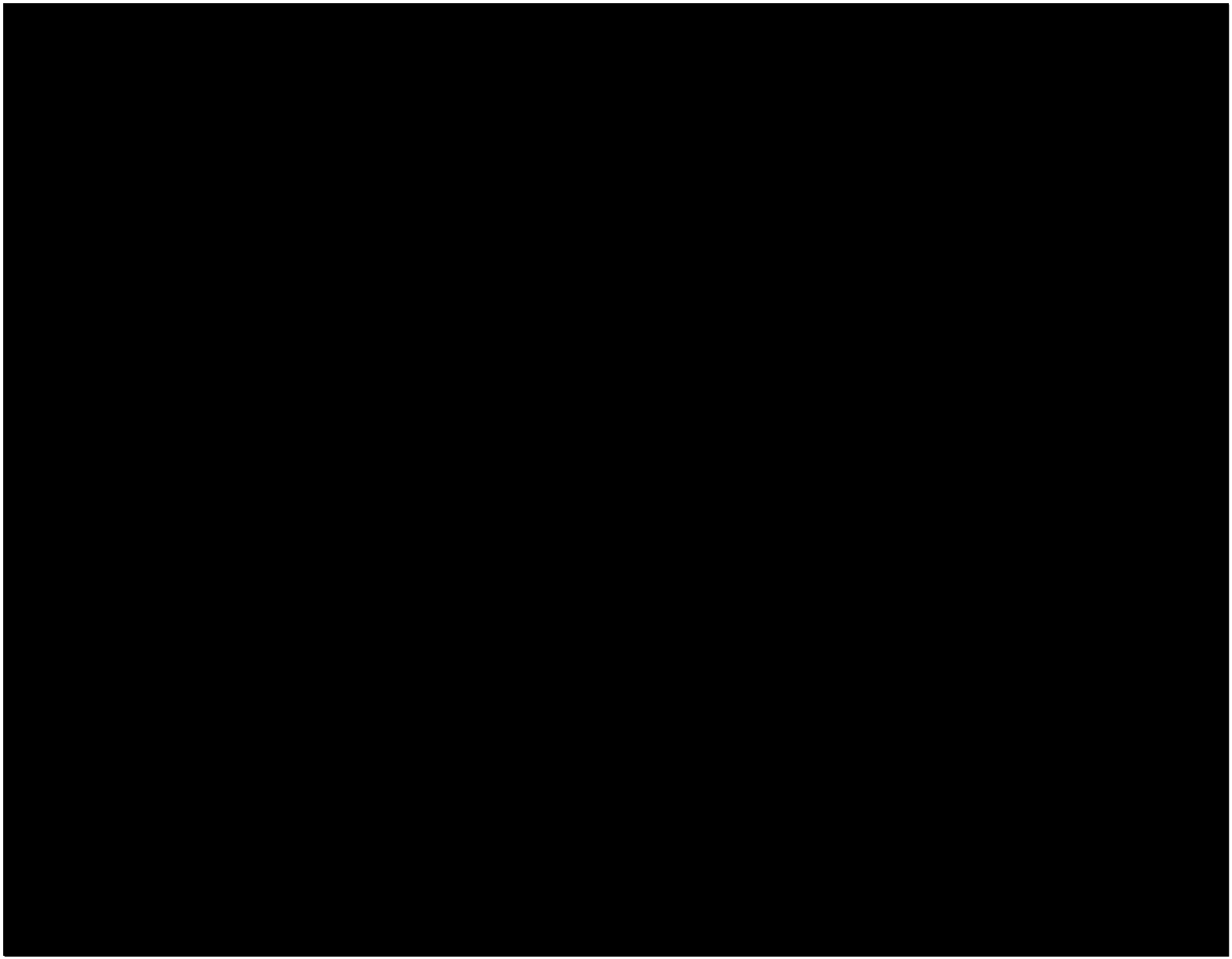
Michael V. Walter, Ph.D.
BioWatch Program Manager
Office Health Affairs
Dept. Homeland Security
[redacted]

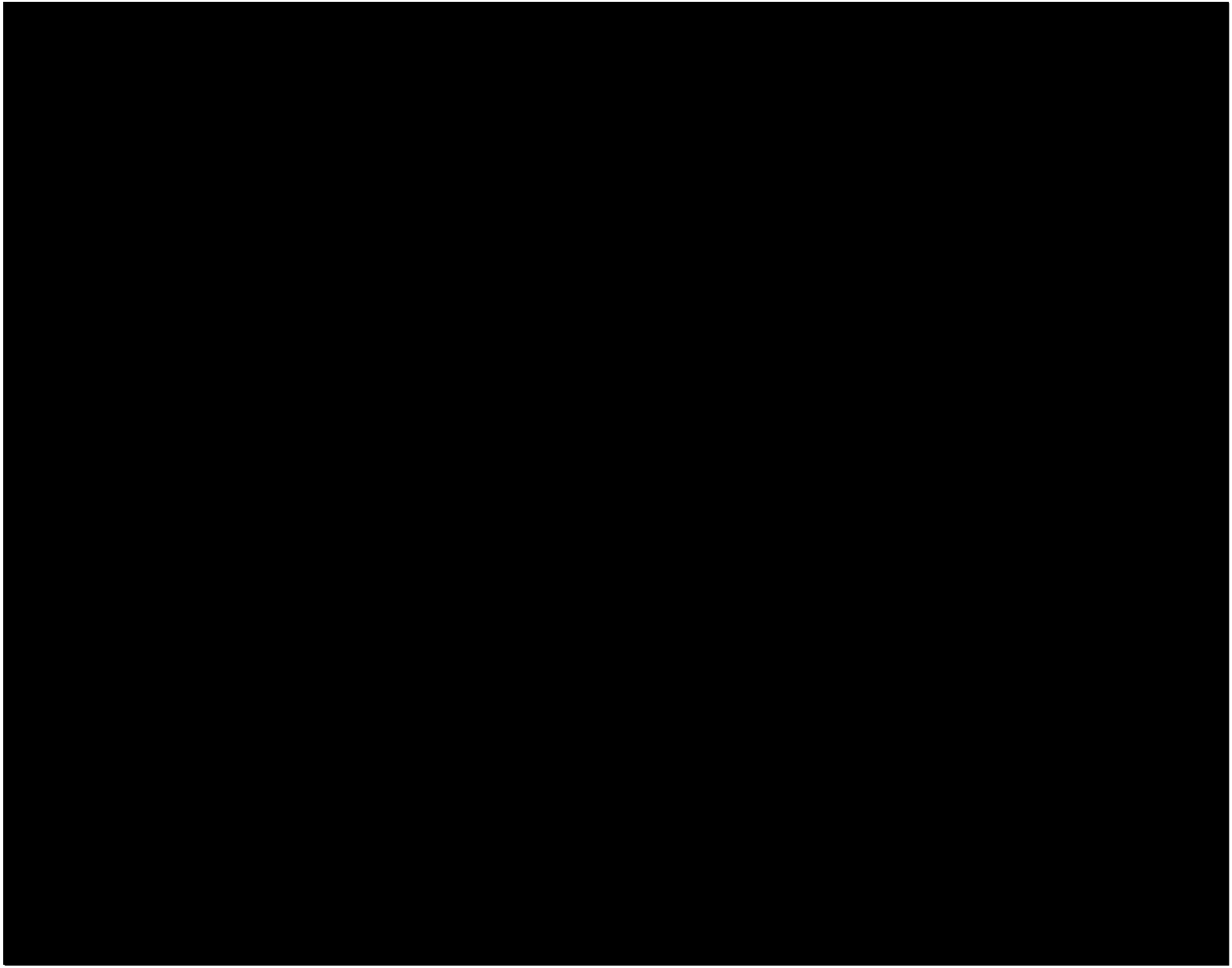
Document 25

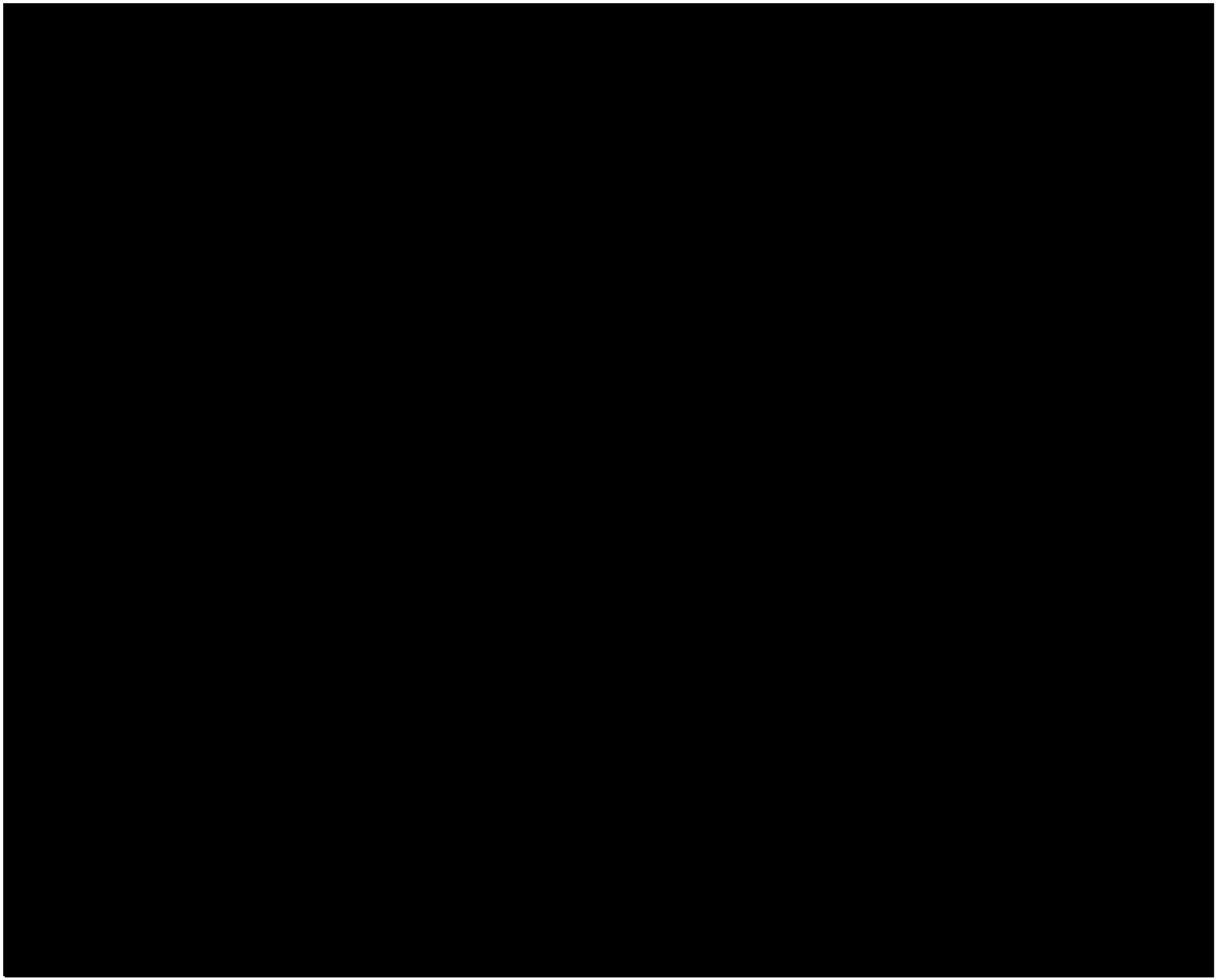


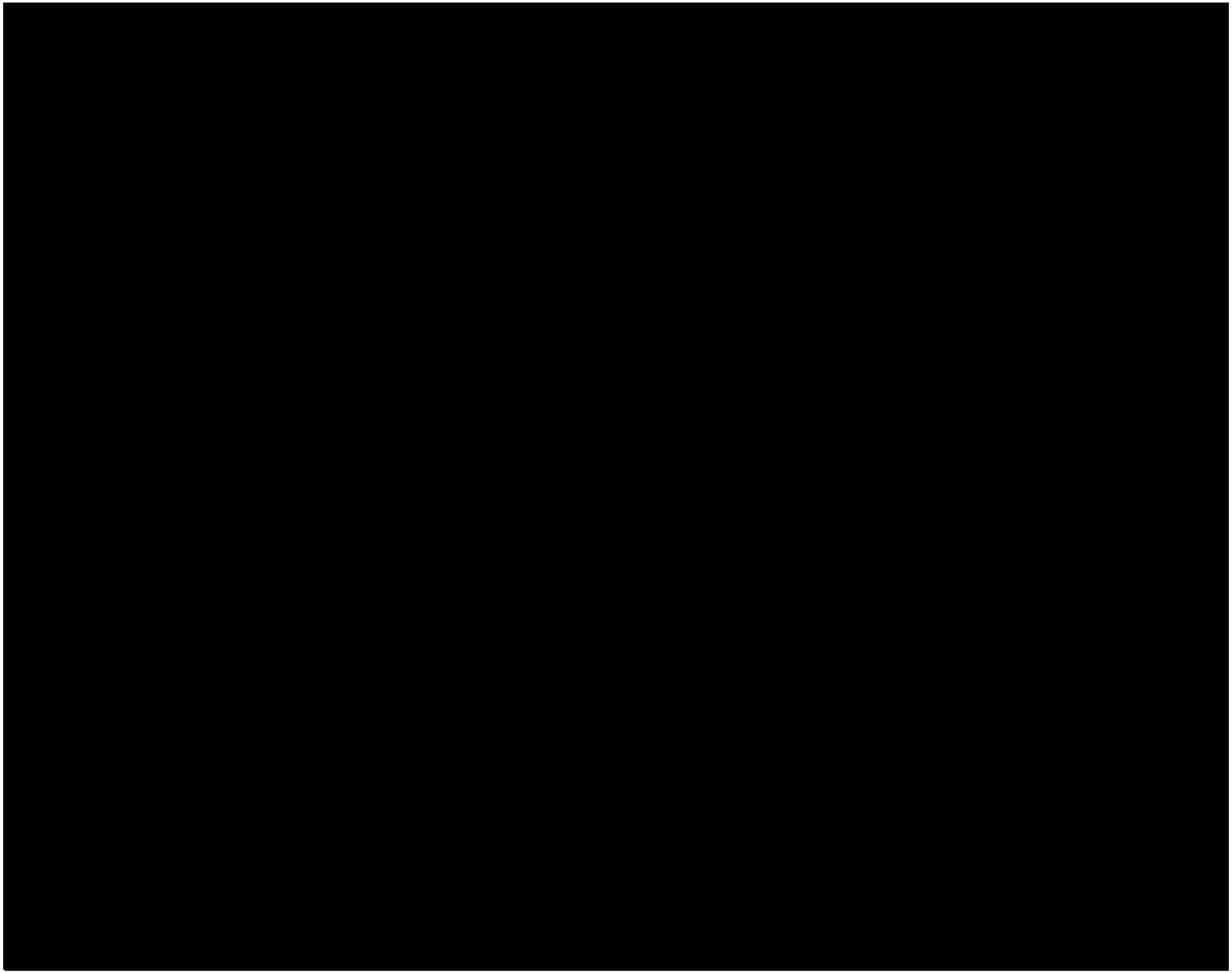


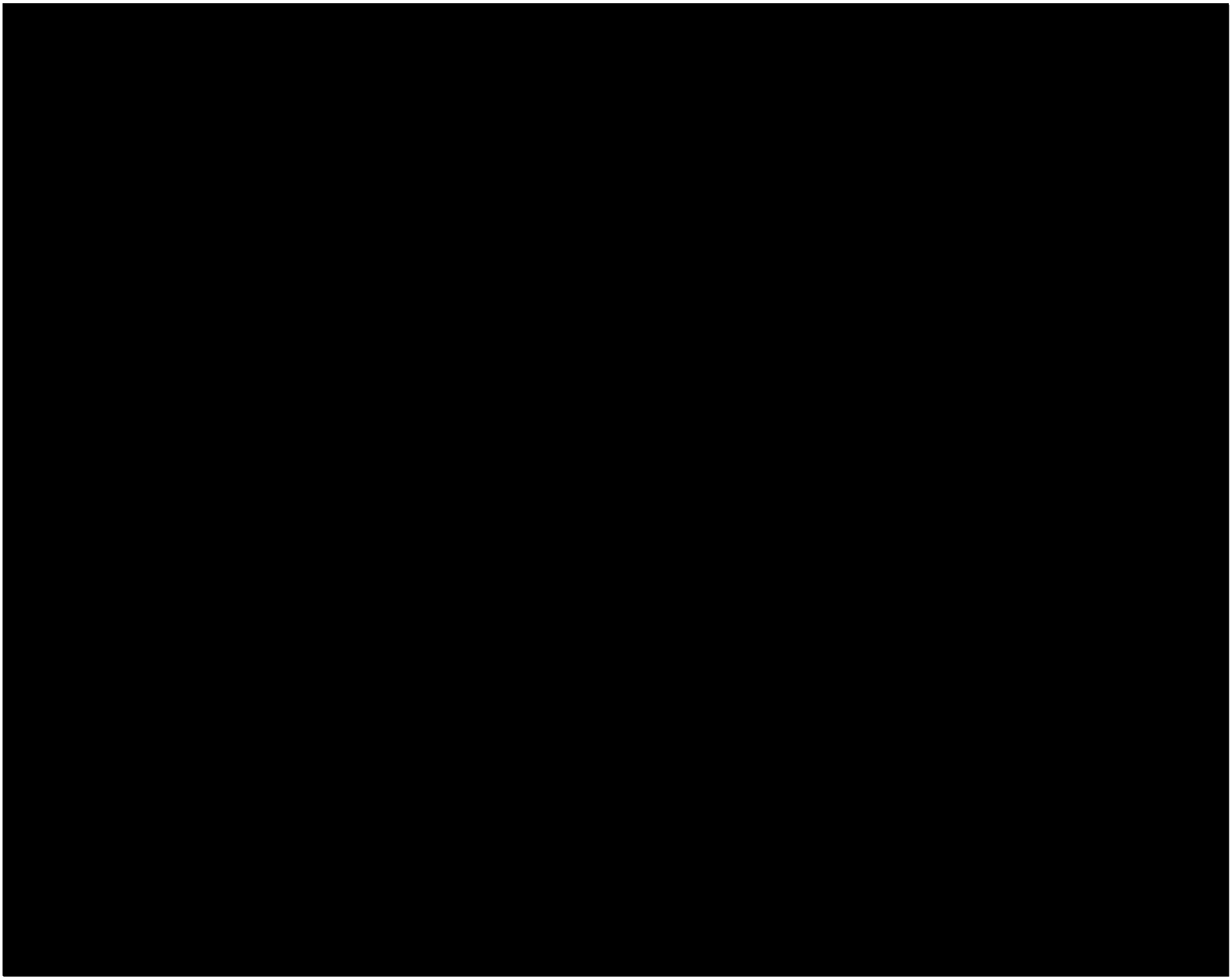


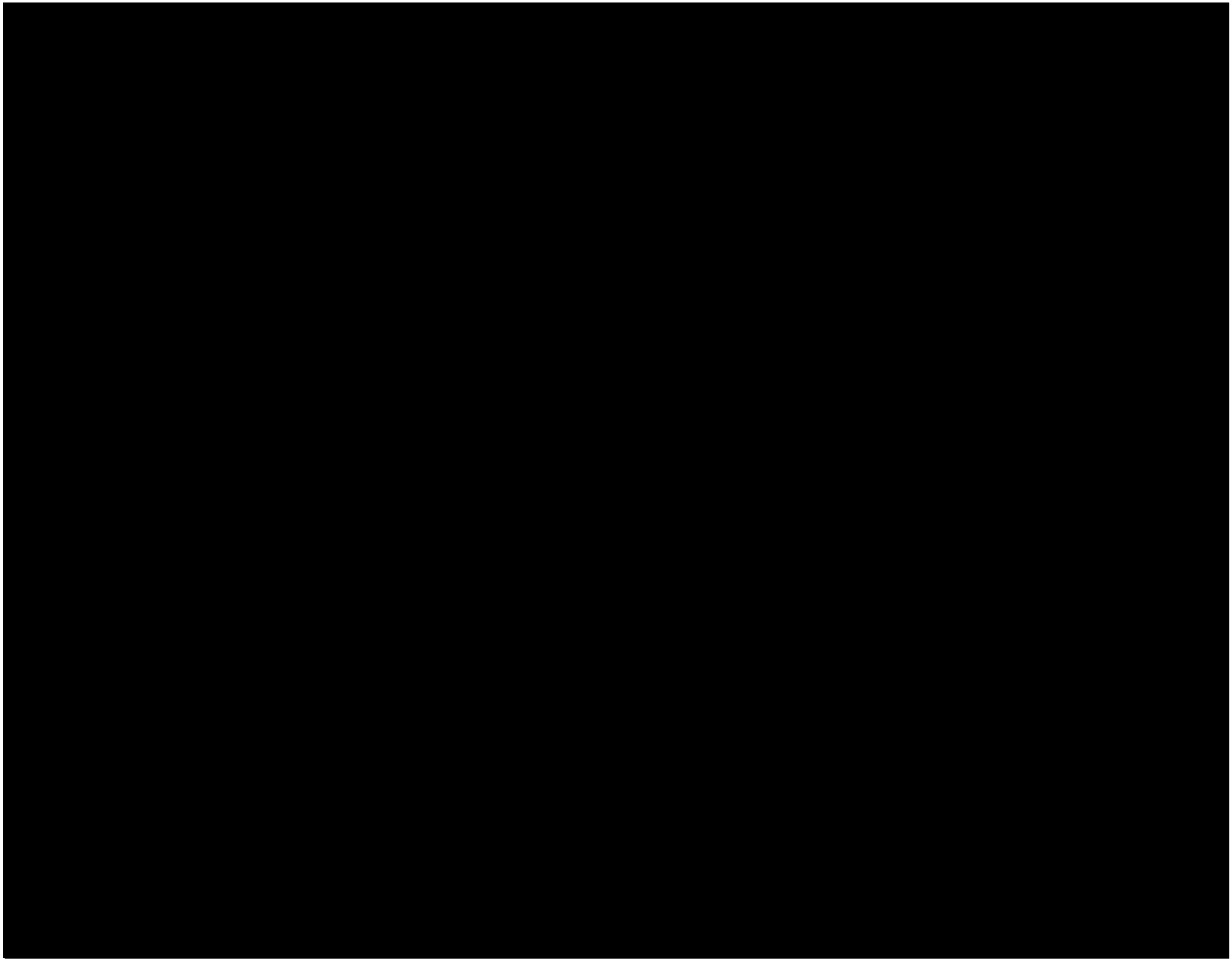


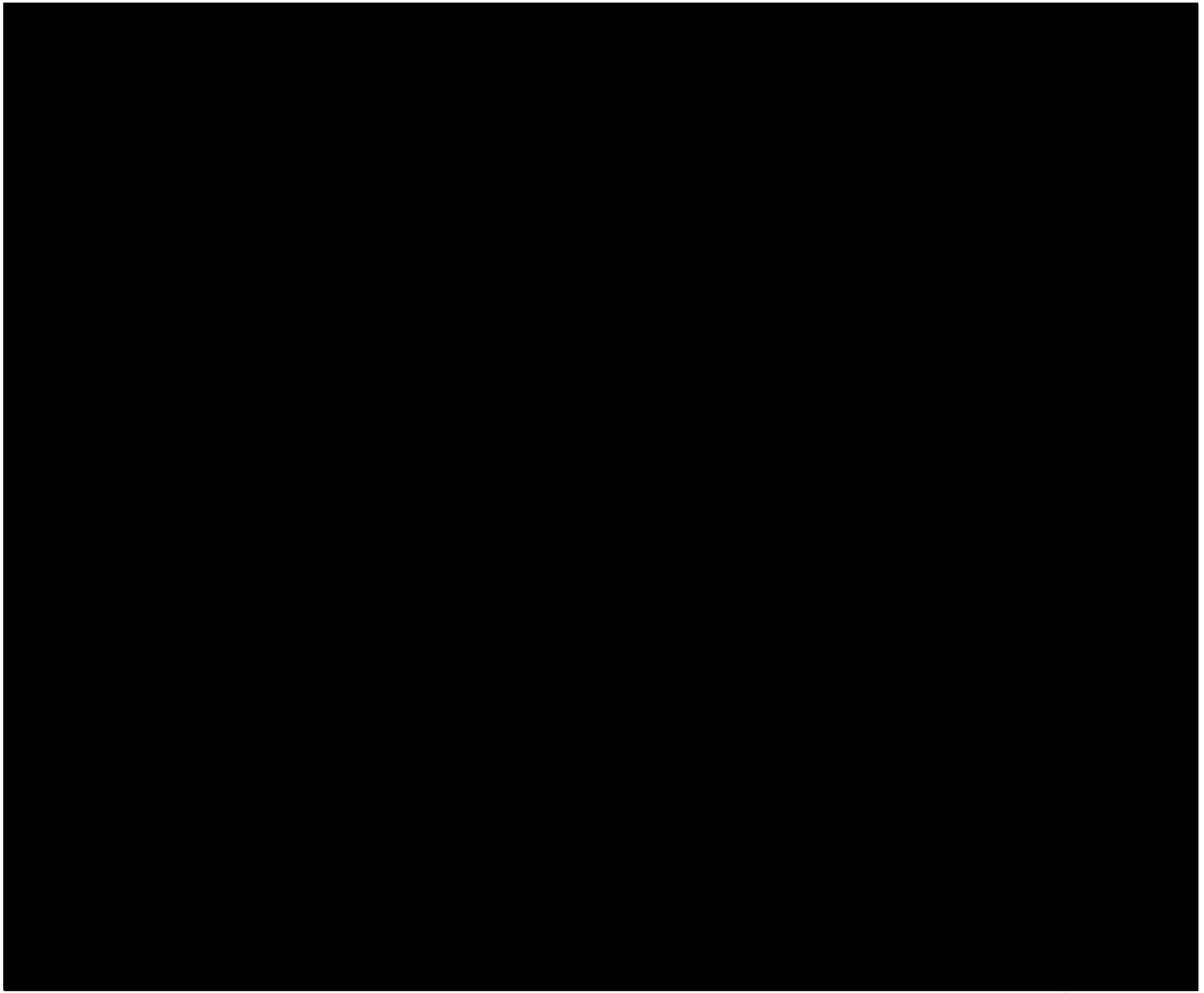


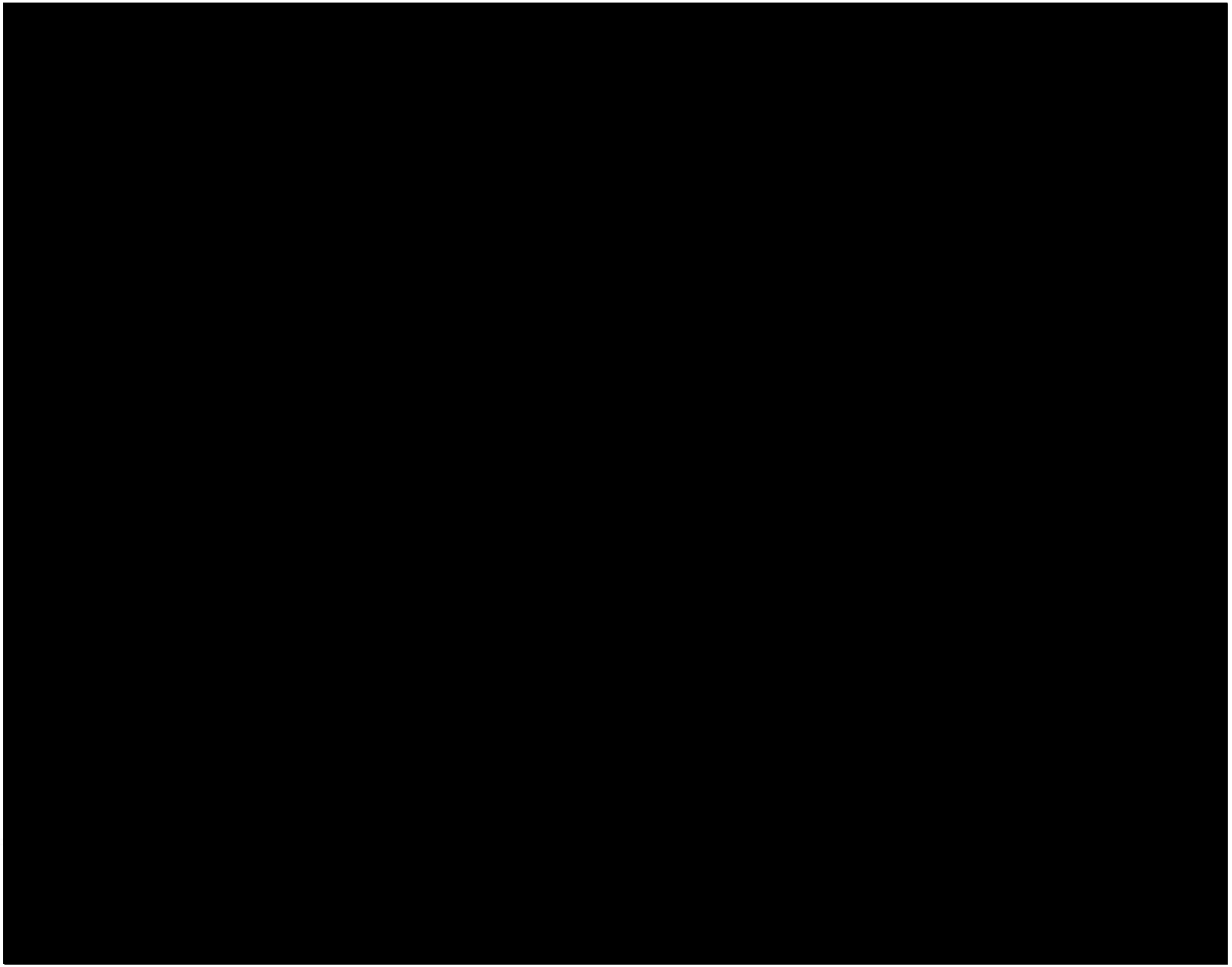


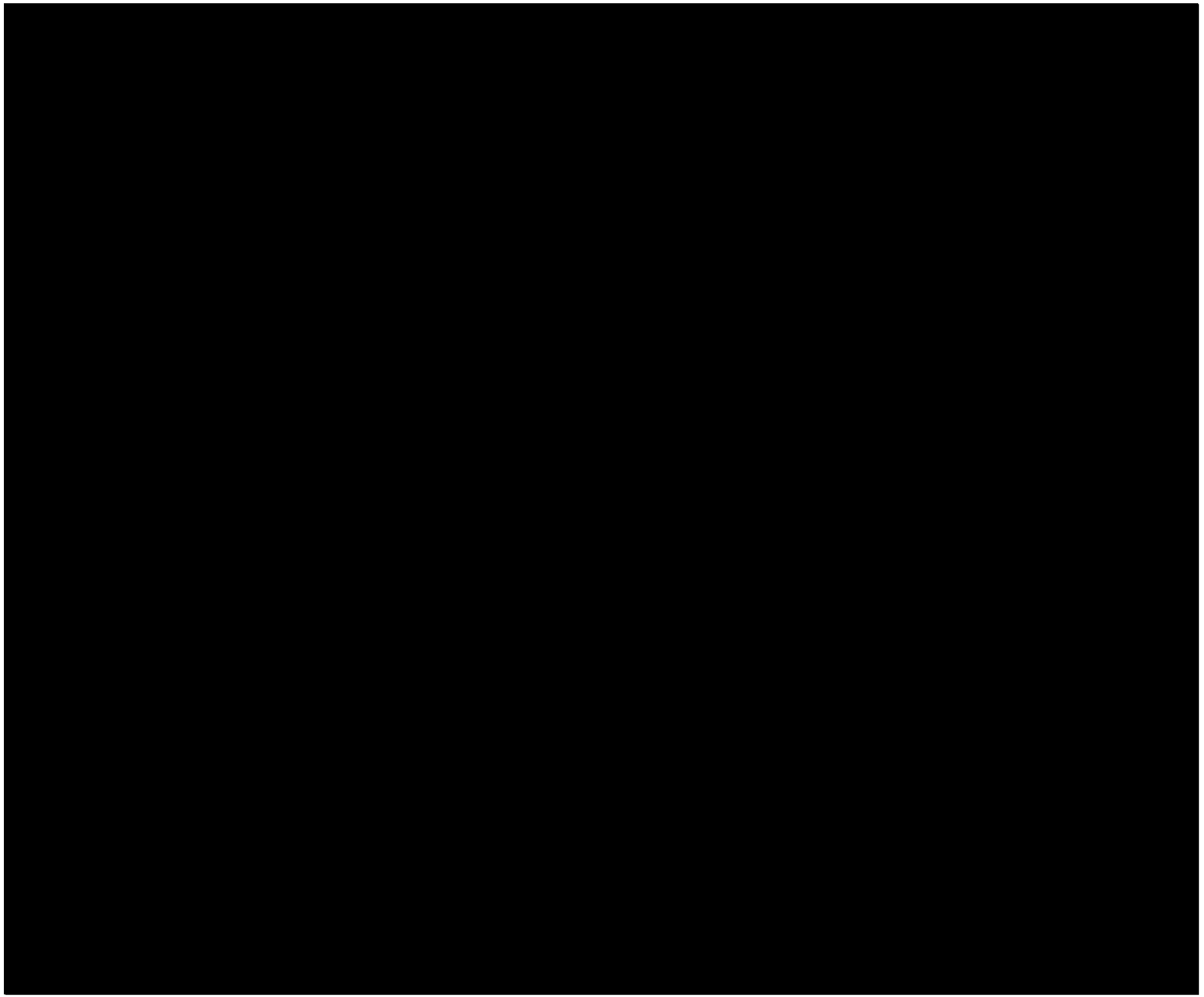


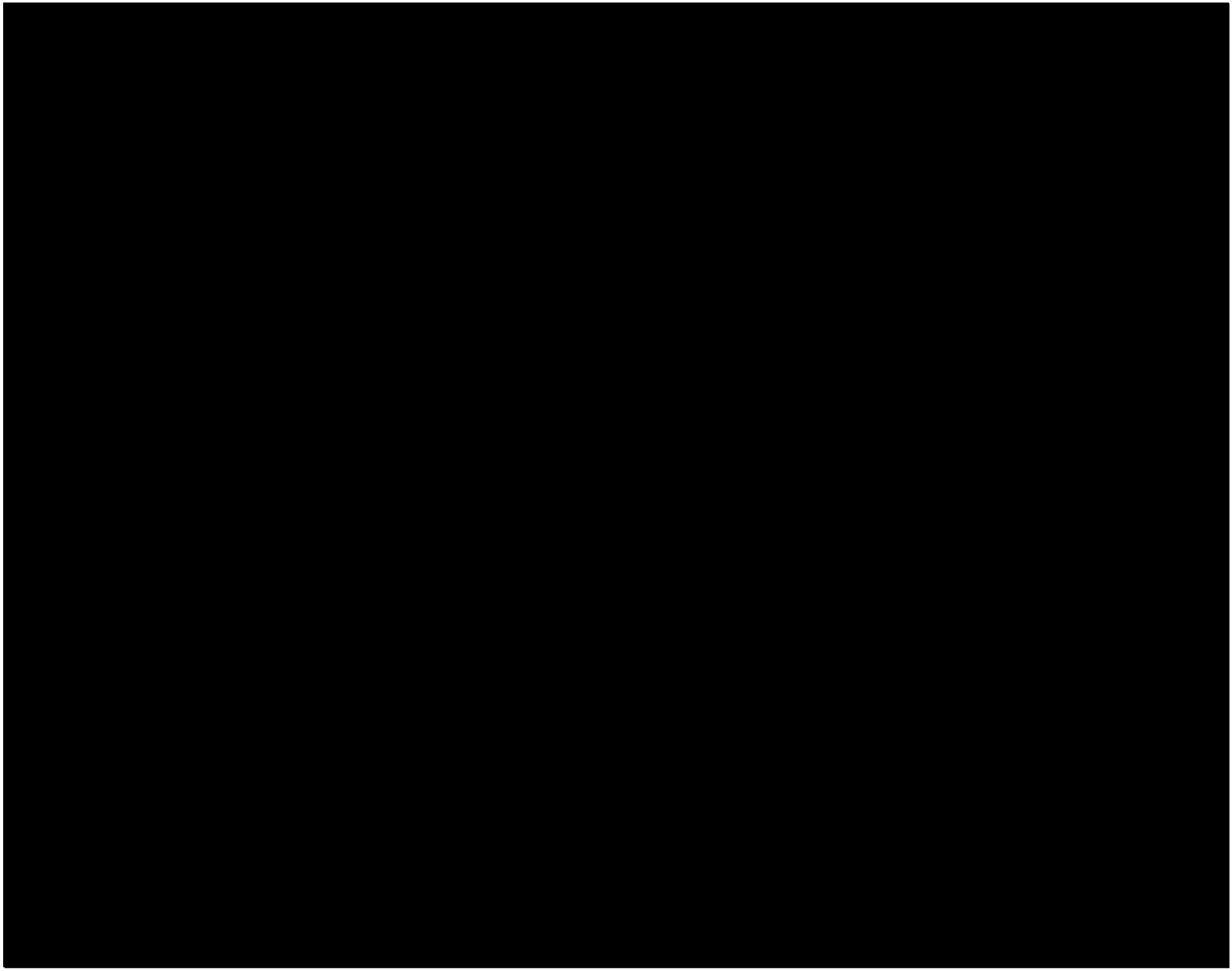


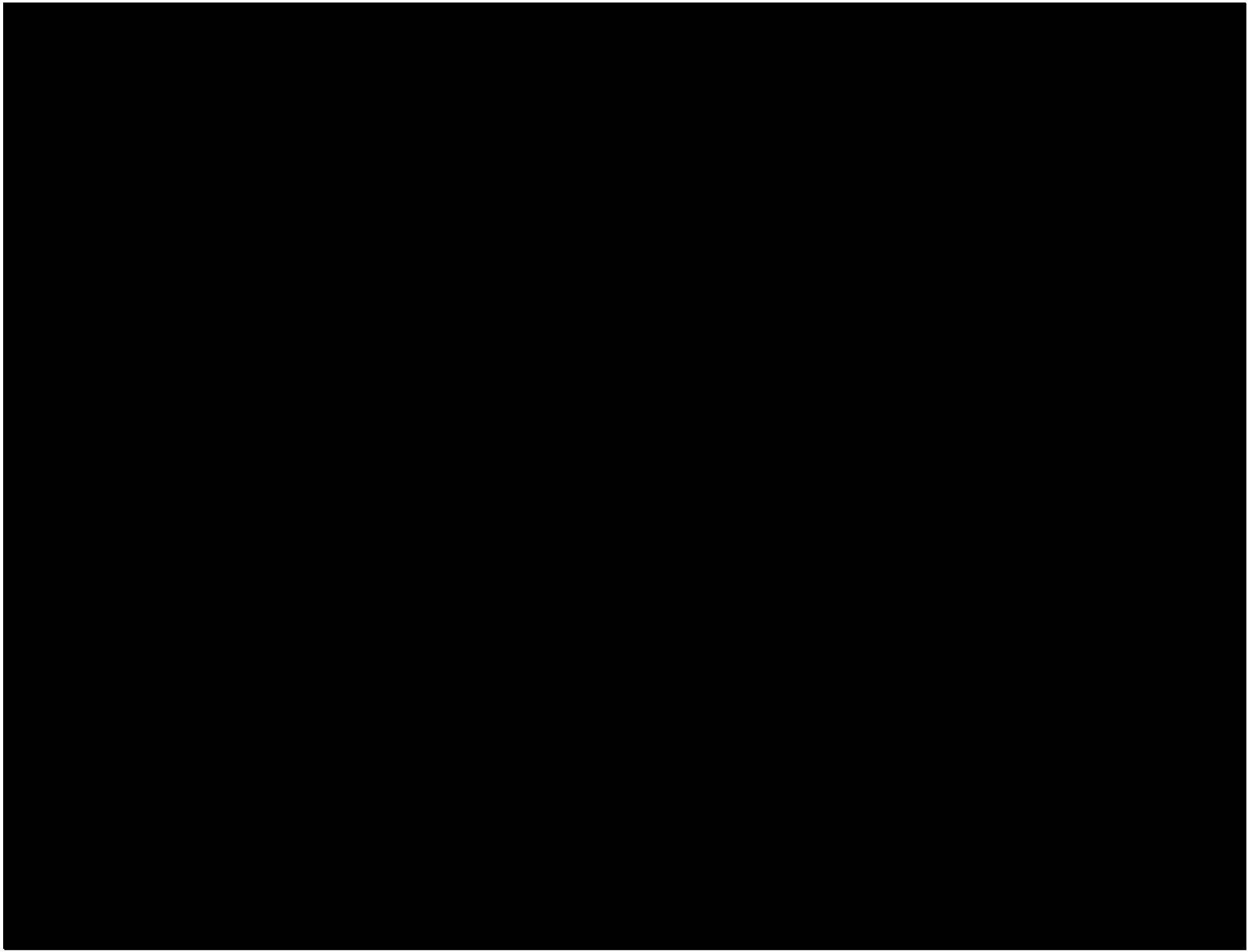


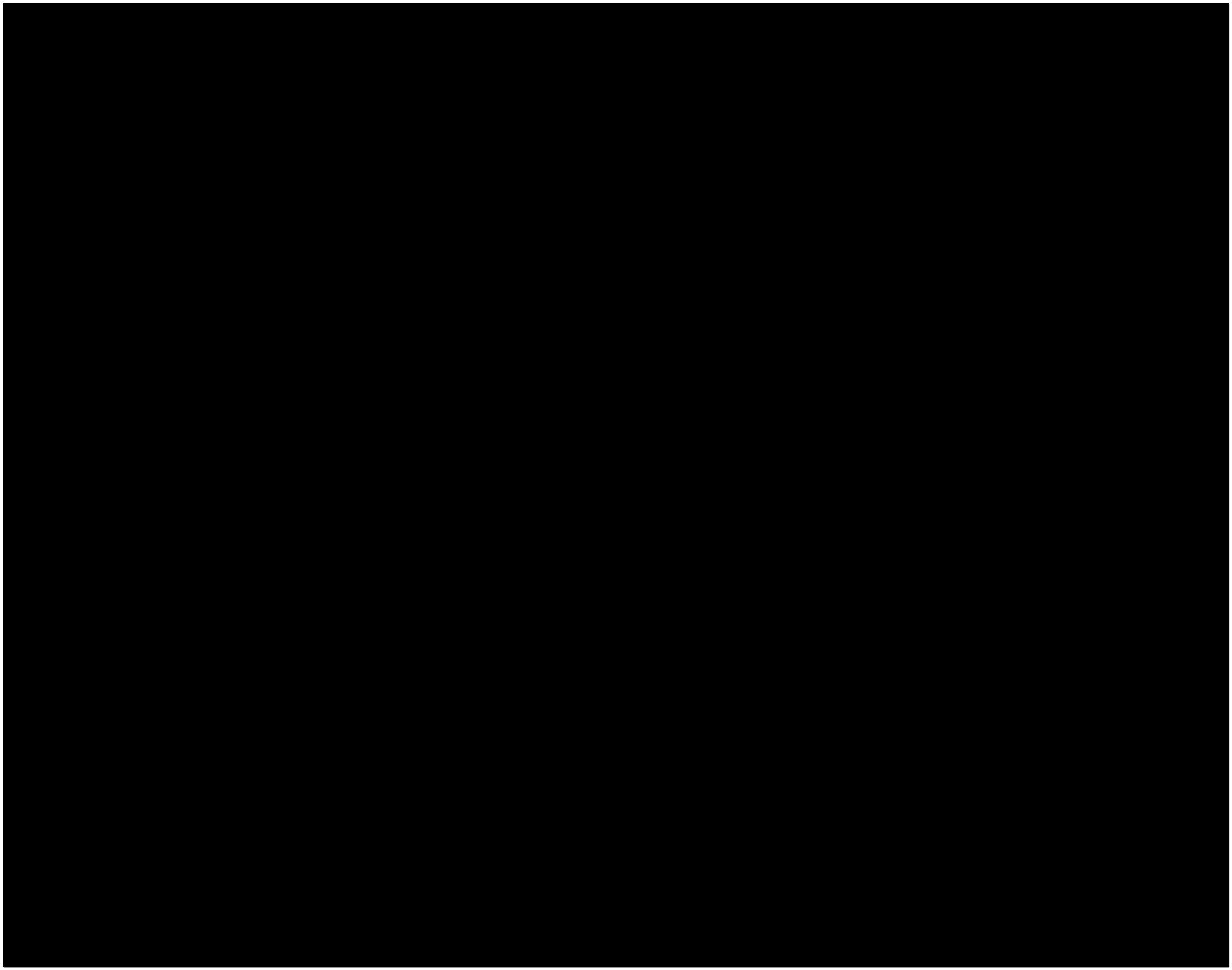


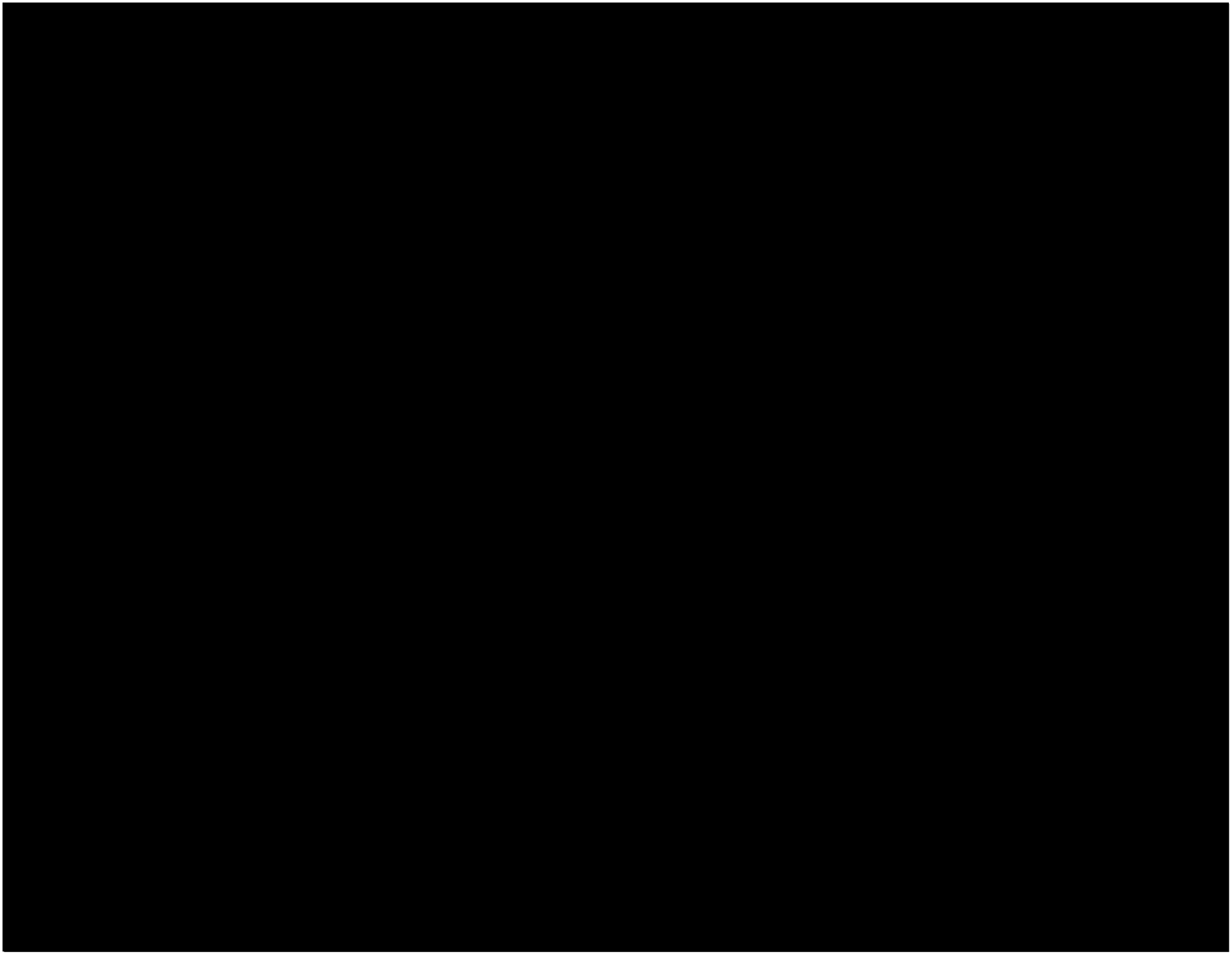


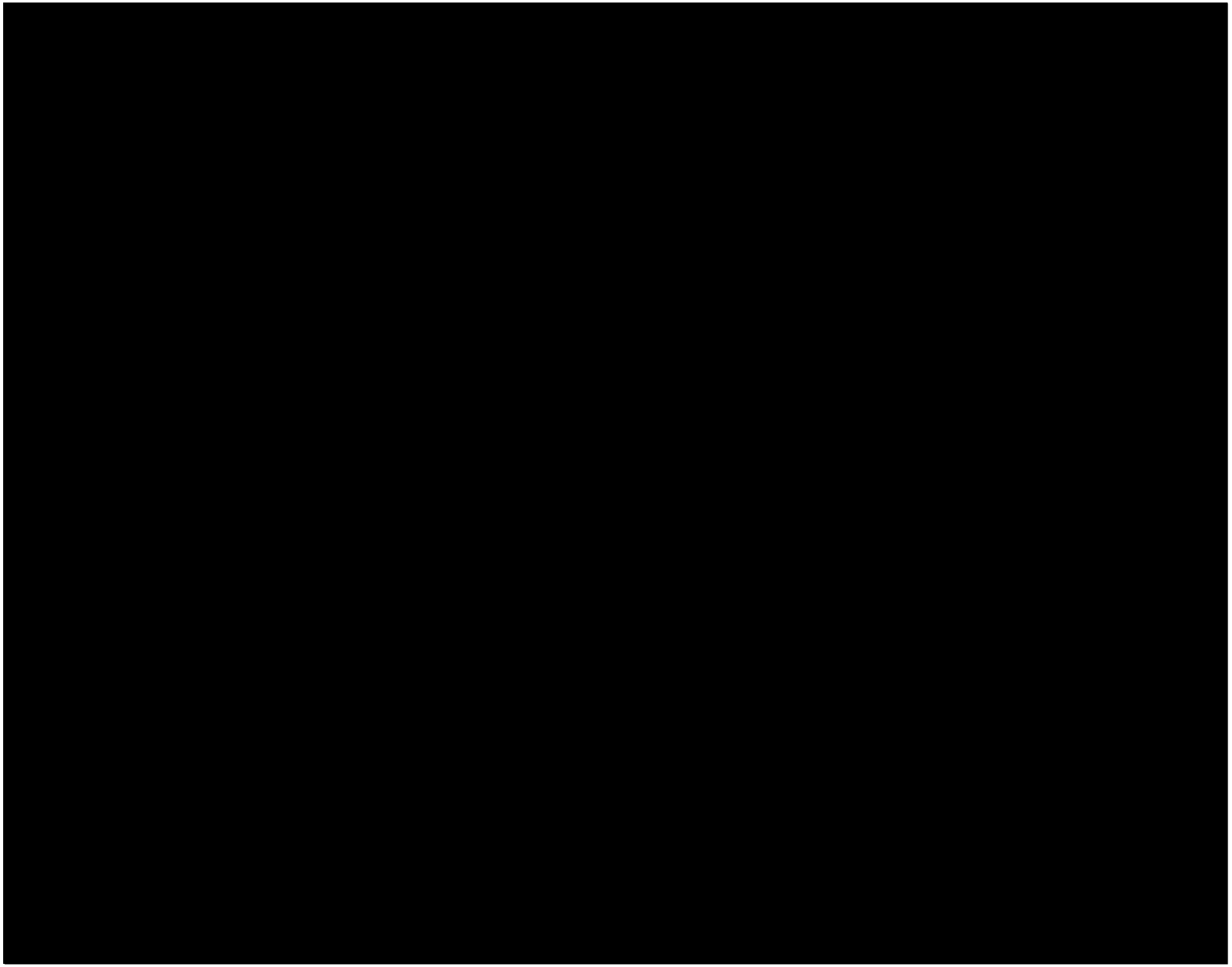


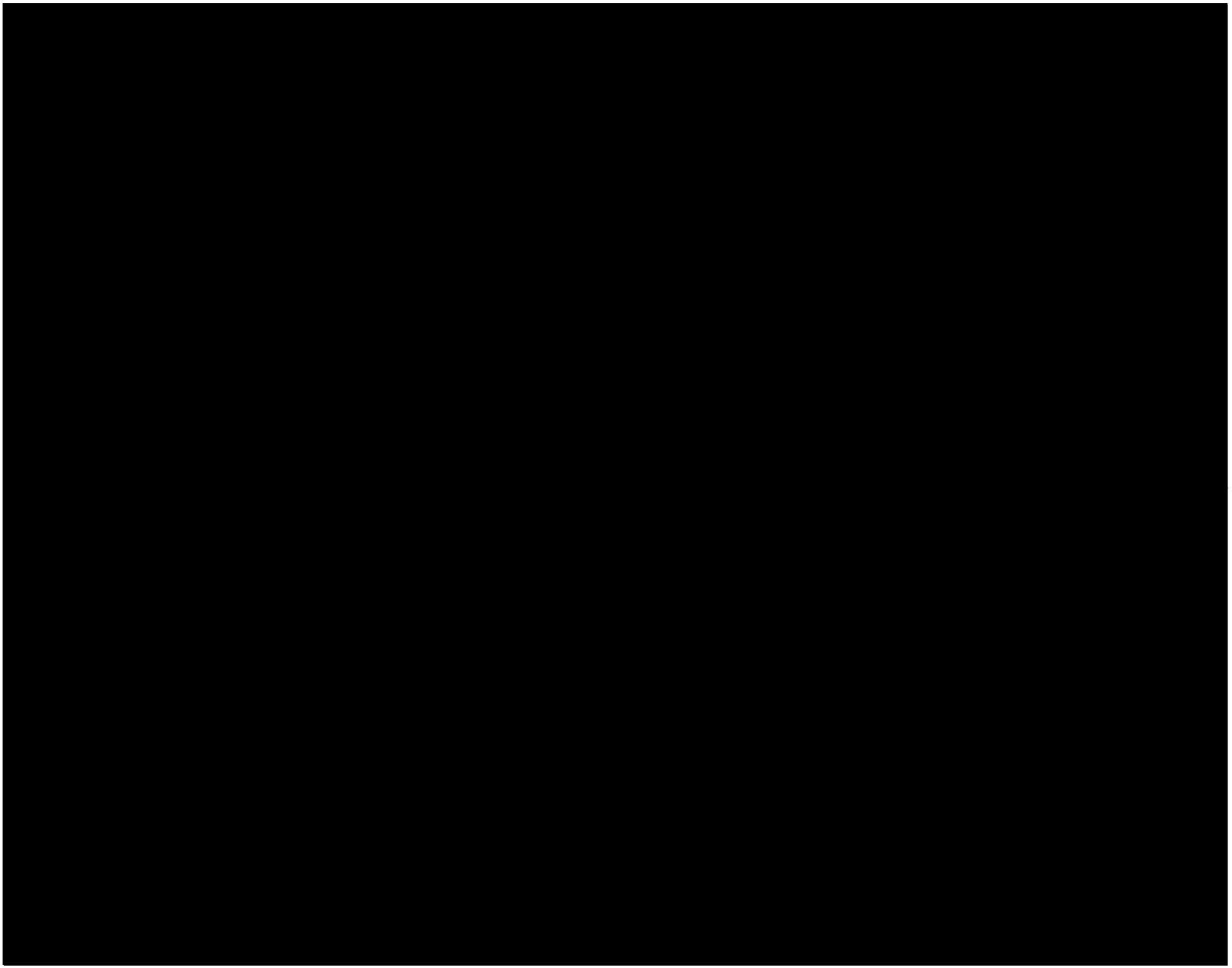


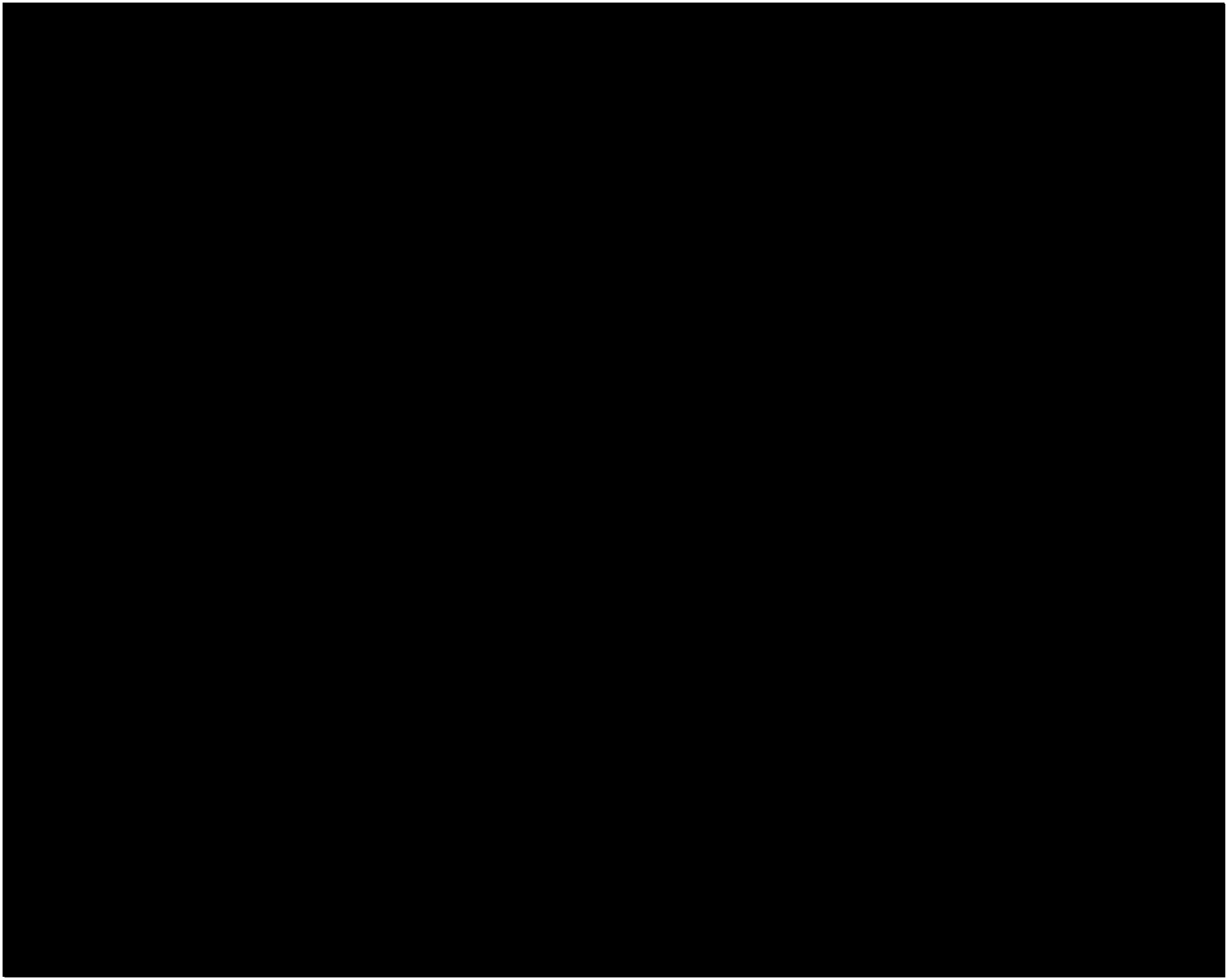


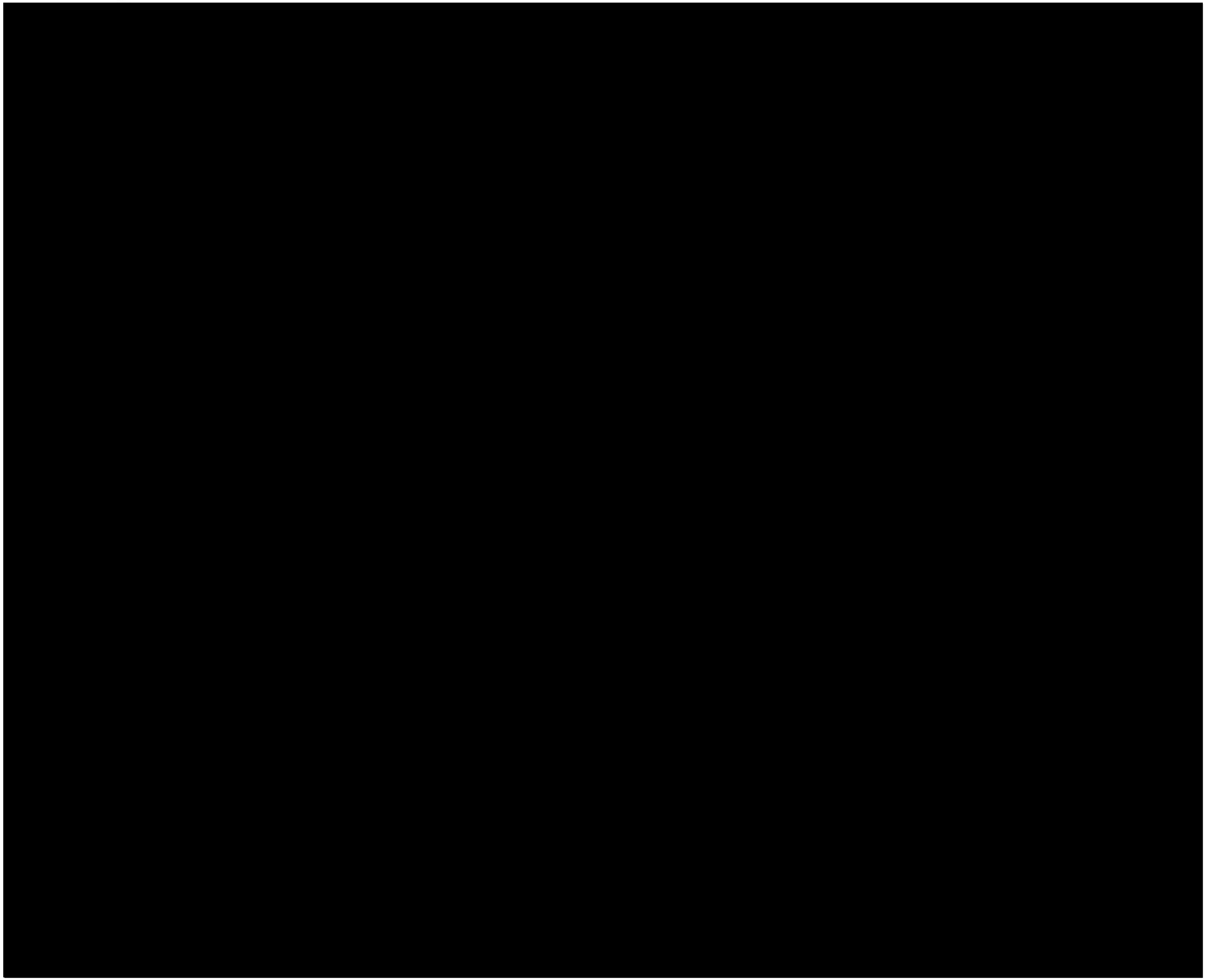


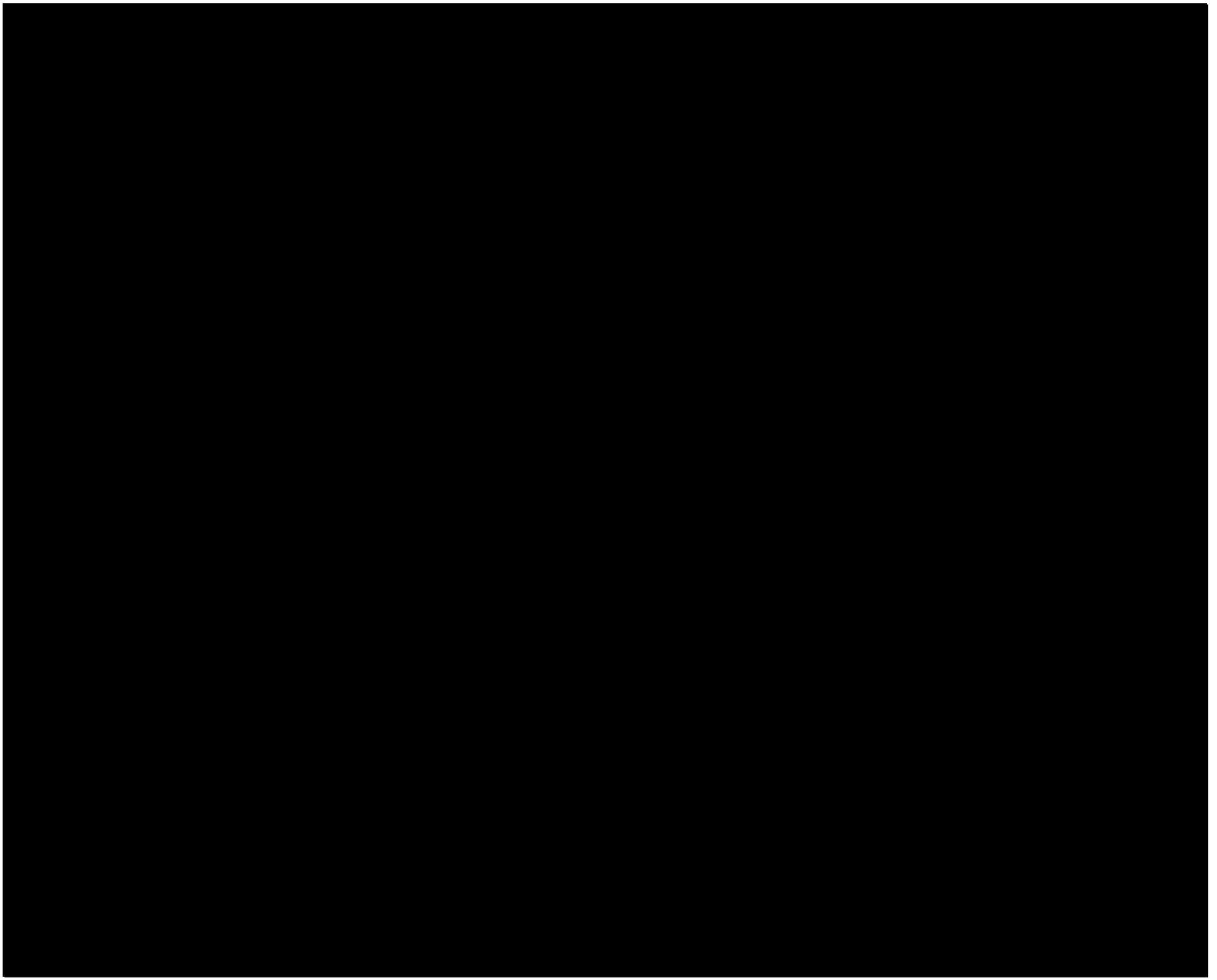


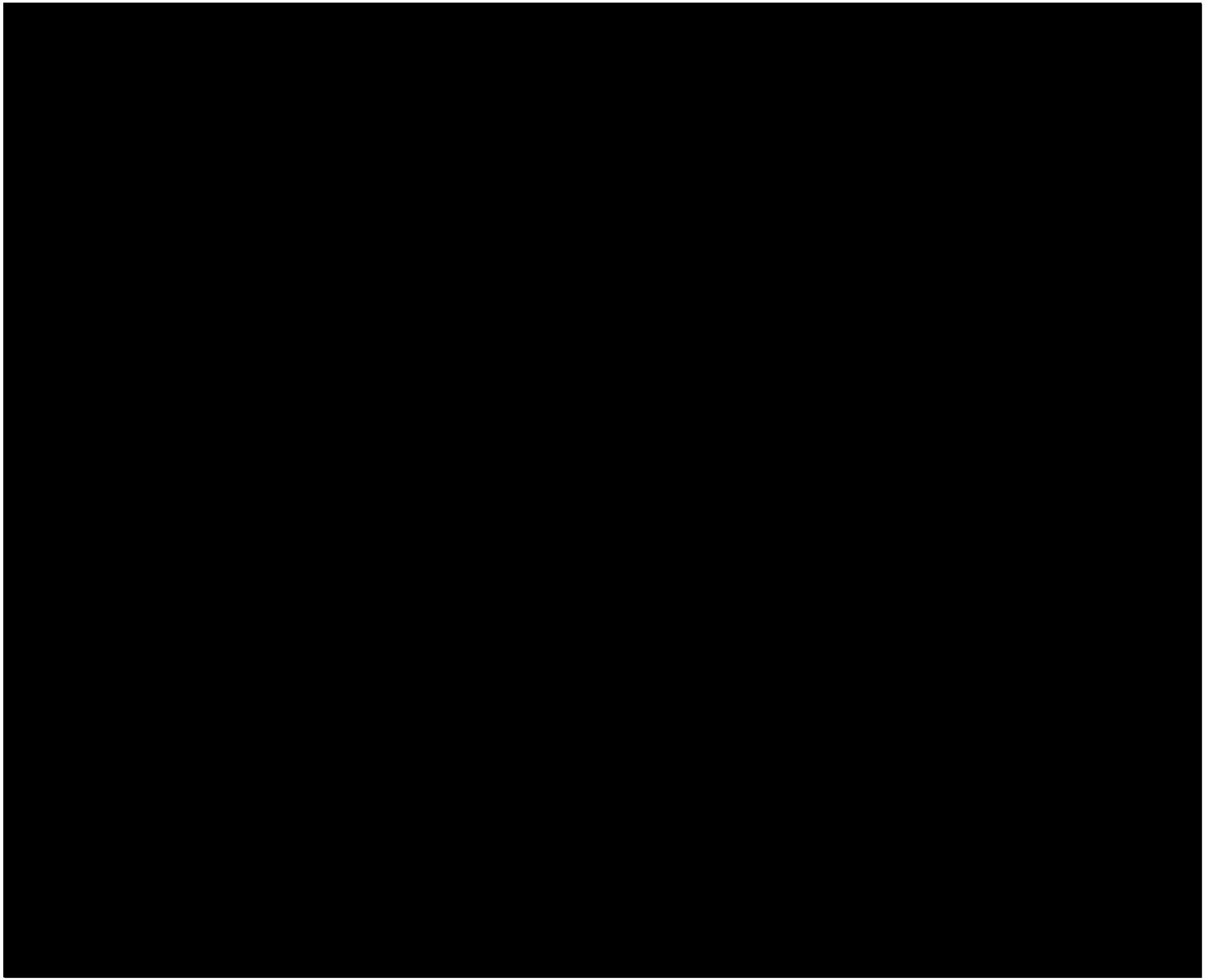


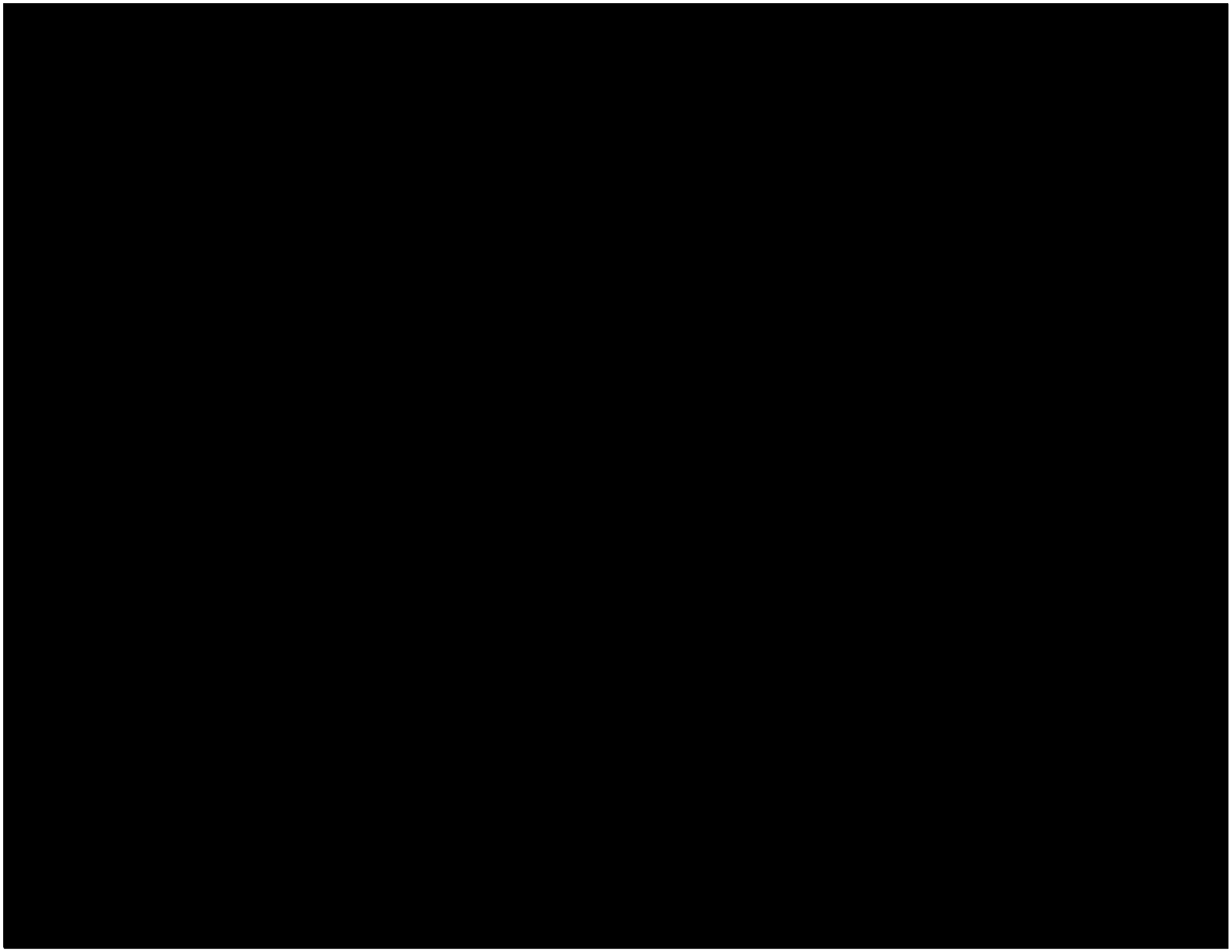


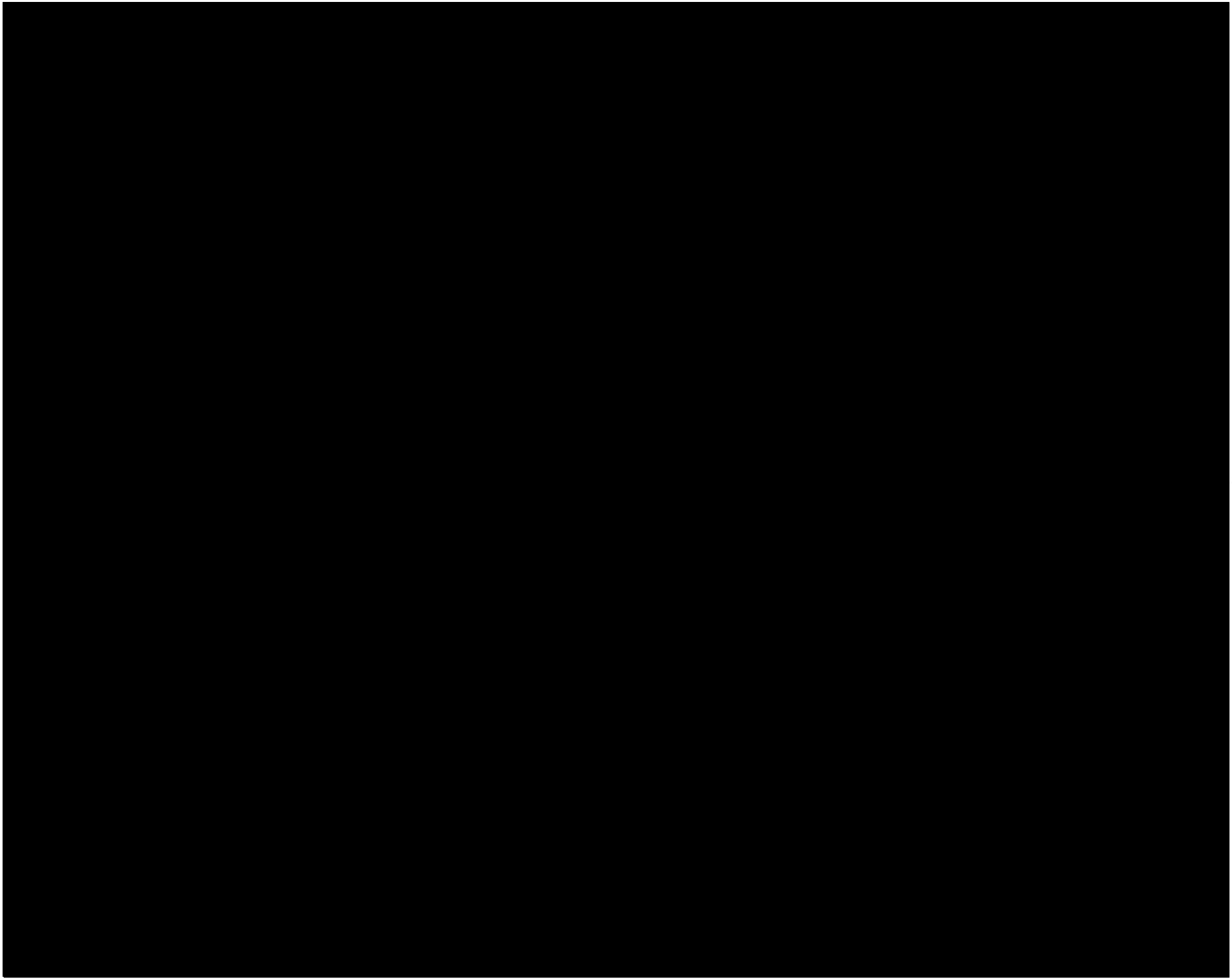


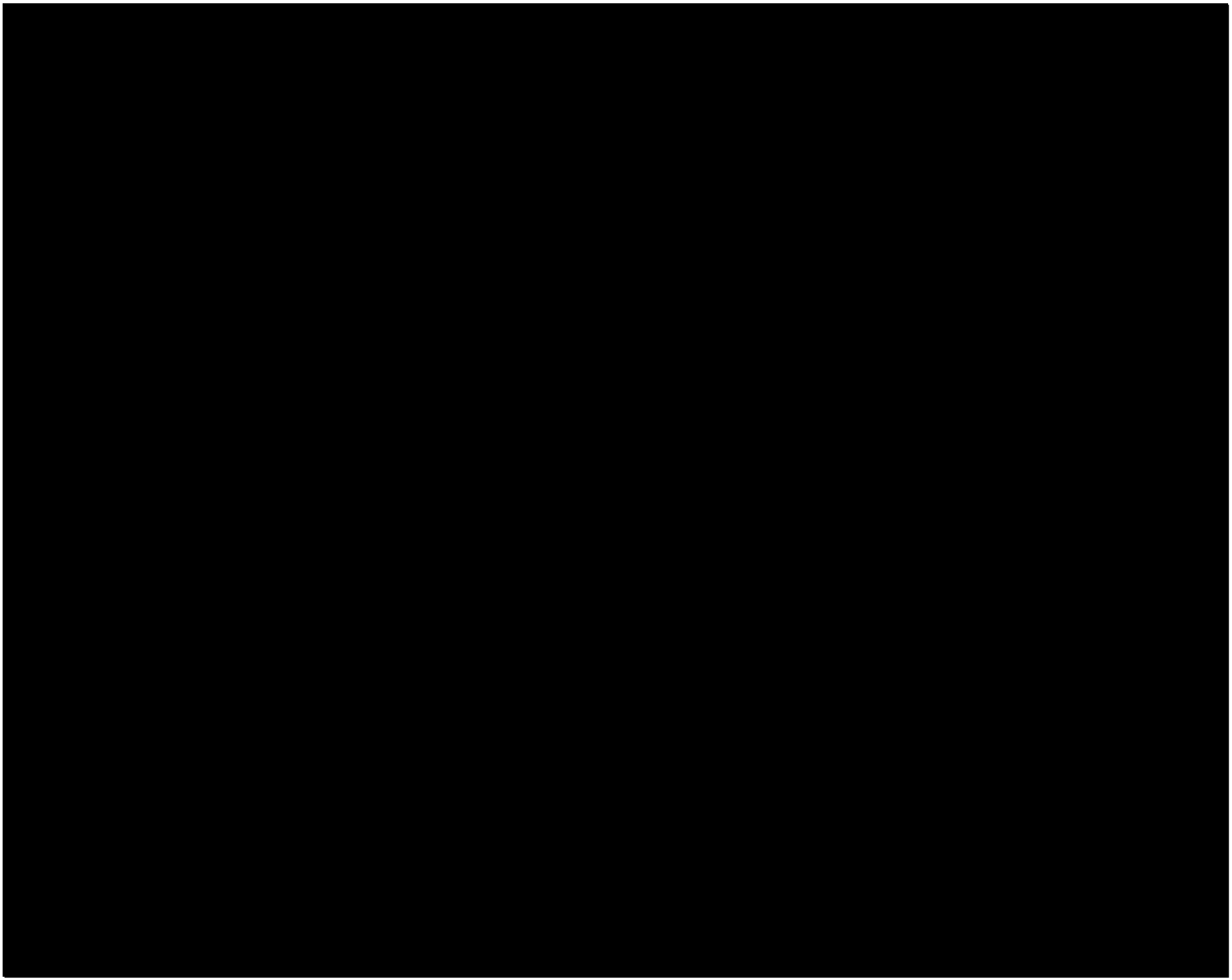












Document 26

Pillai, Segaran

From: Willner, Kristin (CTR)
Sent: Tuesday, January 03, 2012 4:15 PM
To: Pillai, Segaran
Subject: BioWatch read ahead for USST 3Jan12
Attachments: BioWatch read ahead for USST 3Jan12.docx

Electronic version of the read ahead material.

Background:

1) BioWatch Gen 3

Testing conducted on Northrup Grumman (NG) system has failed to meet:

- Assay specificity
- Assay reproducibility
- System sensitivity o[redacted]air
- Mean time of instrument availability (had problem 4 ½ day)
- System failed in subway (Failure of PC to yield results. PCR inhibition – potentially due to metallic dust)

Testing conducted on HS-MFSI system

- Assay reagents had problem of yielding potentially false positive results due to Vic signals in Mix 2 and Mix 3
- Assay issues are fixable
- OHA discontinued any further testing

2) Gen ½ - Lack of understanding
   - System capture efficacy
   - Agent degradation rate
   - Sample processing efficacy
   - Presence of PCR inhibitors and its impact on PCR inhibition for detection
   - The true cost to operate Gen ½
3) OHA's RFP – for Phase II competition
   - Requirements are impossible for any company to meet
   - Designed to support only a single performer/vender – NG
   - Not a far and open competition for vendors/performers to participate and show the value of their system and engineering
   - Clear display of OHA's biases toward a single system to move forward – NG

Path forward:

1) Cease any further testing associated with Gen 3 – since both systems have failed Phase I DT&E
2) Retract the RFP for Phase II Gen 3 competition
3) S&T takes the lead to investigate the current performance of Gen1/2 and what it costs to operate them
   - Perform a system level testing to understand its efficacy and LOD after capture
   - Evaluate each sub component to understand where quick improvements can be made to the system for better efficacy if possible
   - Perform a cost/benefit trade off study to understand the value of such a system/program
   - What does it truly cost to operate Gen ½
4) S&T takes the lead to further evaluate HS-MFSI system with the fixes for its assay
   - Sensitivity
   - Specificity

- System sensitivity to mee[redacted]
- Mean time for failures
- Performance of system in subway

5) S&T conducts a study to understand the benefits of indoor vs outdoor monitoring
   - Look at BTRA – selection of targets
   - Identify high threat and critical venues
   - Determine system's potential value and requirements for indoor monitoring vs outdoor monitoring
6) S&T evaluates potential use of Triggers/Confirmers
   - Understand assay sensitivity
   - Understand assay specificity
   - Understand system sensitivity
   - Mean time for failure
   - Performance in subways
7) S&T evaluates Viable Bioparticle Capture system for potential outdoor use
   - Evaluate the viability of an agent to ensure that our Biomonitoring Detectors were not spooked by threat agent nucleic acids
   - Maintain viability of non-spore forming organisms to support rapid antimicrobial susceptibility testing to initiate appropriate medical intervention
   - Support orthogonal based testing for additional confidence and confirmation (i.e. DFA, Antigen Based Detection, etc.)
   - Ascertain better spatial coverage in support of incident/event characterization for rapid and effective mitigation
   - When distributed geographically, this technology will assist in determining if the event was a point source or a line source release thus supporting attribution through law enforcement related investigation
   - Provide the ability to support detection and characterization of an intentional release of an agent not monitored through the Biomonitoring effort but detected through the Public Health Surveillance System– wider agent coverage
   - Support environmental monitoring for persistence of viable organisms after an event
   - Support Remediation and Recovery related efforts by continuously monitoring for viable organisms to determine decontamination efficacy, reaerosolization/persistence rates and/or agent decay rates
8) S&T redesigns the BioMonitoring Architecture effort:
   - Robust
   - Cost effective
   - Clear benefit
   - Provide appropriate coverage and advanced warning to save lives
   - Embraced by the Public Health community
   - Ensure all data collection and understanding of system performance are taken into consideration
   - Broader agent coverage (other agents including enhanced, advanced, emerging, toxins, etc.)

- If possible, other classes of agents such as chem, rad, explosives and bio detection through a single system

9) S&T reevaluates a system approach for Bio Surveillance/Detection
   - Evaluation of system approach/layered approach
   - Consider clinical surveillance
     - Public Health Surveillance
     - Bio Monitoring effort
     - Other efforts
10) S&T identify high priority investments for the next 5-10 years to pursue for implementation of a robust Bio Surveillance and Detection Program

Document 27

Pillai, Segaran

From: Drabkowski, Douglas
Sent: Monday, April 23, 2012 12:37 PM
To: Pillai, Segaran
Subject: BioWatch

Pillai –

I'm reviewing the updated TEMP from OHA.

The August 23, 2011 TEMP had a parameter for System-level sensitivity (Average air concentration of agents over the collection period) =
Threshold: [redacted] (bacteria/particles)
Objective [redacted] (bacteria/particles).

However the updated January 20, 2012 TEMP has a parameter for System-level sensitivity they call: "Total Integrated Concentration" still described as the average air concentration of agents over the collection period but lists the Threshold/Objective KPPs as follows:
Threshold:
Indoor: [redacted] x minutes for bacteria)
Outdoor: [redacted] x minutes for bacteria)
Objective:
[redacted] x minutes for bacteria)

What kind of game are they playing with these system-level sensitivity numbers?

[redacted]

Document 28

S&T Chem-Bio Division Review and Comments
BioWatch Documents – June 14, 2012

DOCUMENT: Acquisition Program Baseline (APB) for BioWatch Gen-3 Autonomous Detection System (OHA BioWatch APB Version 1.1, Dated April 16, 2012

Comments:

- **p.8 "Anticipate deploying next generation technology to replace an aging Gen-3 system."** Comment: Funding to develop and/or deploy such a technology not identified.

- **p.8 "Gen-3 acquisition will be executed in two-phased approach to engage multiple vendors, provide maximum competitive opportunities for industry, and provide flexibility in selection of high performance/cost-effective solution. Phase II will have multiple awards for Performance testing with a down-selection to one vendor for the 4-jurisdiction OT&E."** Comment: This does not indicate a sole source process option, only a process to engage multiple vendors in Phase II.

- **p.9 "Phase I effort will provide sufficient information to determine viability of the technology for further investment."** Comments: The information provided to DHS S&T for review provide serious concerns about the inability of the Northrop Grumman and HSSI technologies to fully meet Phase I requirements. It's important to note that the Northrop Grumman technology is currently going through further development to improve system sensitivity as it had 100-fold lower system sensitivity than what was desired in the operational requirement document. This is problematic as the requirement for Phase I testing was to evaluate only "mature" technologies. The Phase I source selection process included entry criteria to ensure vendors could provide "comprehensive, logical and detailed designs for mature autonomous detection systems." The Northrop Grumman (NG) system also failed to meet 1) assay specificity, 2) assay reproducibility, 3) system sensitivity, 4) mean time of instrument availability (had problems every 4.5 days), and the system failed indoors due to PCR inhibition of metallic dust.

OHA PPT Slide. Partial List of Requirements not met by NG testing

Gen-3 Requirements (NG): Initial Analysis

Paragraph		Requirement	Status
4.1		BioWatch Agents	Met*
4.3 System Performance			
	4.3.1	Autonomous Operation	Met*
	4.3.2	Detection Cycle	Met
	4.3.3	Time to Detect	Met*
	4.3.4	System Sensitivity	Not Met
	4.3.5	Probability of Detection	Not Met
	4.3.6	Probability of False Positive	Not Met
	4.3.7	Public Health Actionable Assay	Not Met
	4.3.8	Viability	Not Tested
	4.3.9	Reporting	Met*
	4.3.10	Archiving	Met / Partially Tested
	4.3.11	Self-Assessment	Met
	4.3.12	Failure Analysis & Fault Isolation	Not Met

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*Met within test limitations

20

- **p.13 Program Cost:** [1]

a.	Acquisition	(T) $903M	(O)	$856M
b.	O&M	(T) $6,529M	(O)	$5,831M
c.	LC Cost	$7,432M		$6,688M

[1] Note: Baseline Threshold costs at 65% confidence level. Baseline Objective costs at 50% confidence level.

DOCUMENT: 20120509 Gen-3 APV V1.1 based on 20120321 timeline v2.pdf

p.11 Section C.1: "Performance Parameters":

Comments: It appears that the system-level sensitivity measures are listed incorrectly for both threshold and objective. They are listed as organisms/m^3 x minutes when they should be listed as Total integrated organisms with just the number of organisms [redacted]

DOCUMENT: BioWatch Gen-3 Systems Engineering Life Cycle Tailoring Plan (Version 1.0) Jan 20, 2012 Comments:

- **p.1 "The Gen-1/2 system detects 5 Agents of Biological Concern and provides outdoor coverage for approx. [redacted] in each of the 30 jurisdictions – [redacted], and for 5 indoor facilities".** Comment: On what basis is this coverage determined? What is the system sensitivity of the current Gen 2 system?
- **p.4 "After completing Phase I the program also conducted a detailed requirements analysis through Sandia National Lab. The study assessed the utility of the autonomous detection systems with varying degrees of sensitivity in terms of detection timeliness, population coverage, and lives saved during a bioterror attack. This study was completed in January 2012. Based on the results, DHS decided to revise the ORD threshold requirement for System Sensitivity to reflect a more realistic articulation of the minimum acceptable level of performance."** Comment: This raises concerns as the sensitivity requirements are critically important to ensure meeting appropriate technology Probability of Detection (Pd) metrics/requirements. In other words, if system sensitivity is increased to [redacted] over a 6 hour time window, the Pd will be in the range of [redacted] with 40 detectors deployed. In addition, a cost-benefit analysis should be performed to support a possible change to the ORD.
- **p.6 "The total life cycle cost is estimated at $4,347M at the 50% confidence level".** Comment: Why is this value different than what is listed above in APB document?
- **p.12 "Offerers for Phase II are not required to participate in Phase I; however, they must demonstrate that their proposed technology is ready for low-rate initial production." "The ARB approved the Phase II acquisition strategy for full and open competition for a "total system solution".** Comment: A multiple vendor evaluation and approach is most appropriate for such a large and visible acquisition program, and more importantly was approved by ARB. This will allow for a comprehensive understanding of the best system available to support the BioWatch mission.
- **P.26 "Assay Evaluation: "Conducted at LANL to verify candidate Gen-3 detectors' assay performance in terms of sensitivity, specificity and repeatability. The objective was to ensure the assay meets Gen-3 operational requirements and reduce the risk of the detector generating erroneous signals.** Comments: Both technologies tested had significant deficiencies and both did not successfully complete Phase I testing. The Northrop Grumman (NG) assays by agent were shown to be [redacted] less sensitive than the current threshold requirement (per OHA) In addition, the Assay Evaluation Report generated

Comments:

The Northrop Grumman (NG) failures were so significant that OHA proposed major engineering modifications to the NG technology that included changing out the Collector, replacing the Analytical Subsystem Reader, and incorporating a sample preparation module that required several months to one year to complete. OHA awarded three (3) contracts for engineering change proposals. Such changes necessitate that the NG system be re-tested through Phase I T&E to understand if it meets much lower system-level sensitivity requirements! Both NG and HSSI/MFSI systems both didn't successfully pass Phase I testing. However, one system, NG was modified by OHA with Federal funding, and not the other. This poses questions regarding disparate decisions for testing, evaluation, and modifications of the NG system.

OHA Planned Modifications to Northrop Grumman System:

	ECP	Description	Estimated Improvement to Sensitivity
1	Enhanced Collector Concentrator	Replace SASS with continuous sample flow wetted wall cyclone (WWC) collector and inline Virtual Impactor (IVI) particle separator	• [redacted]-10X improvement (at [redacted]) • Includes improvements in sampling efficiency and retention efficiency • Based on DHS S&T and NG testing
2	Enhanced Analytical Subsystem Reader	Replace flow cytometry based LX-200 reader with imaging based MagPix reader	• Unknown
3	Improved Fluidics Valve Material	Replace soft fluidics valve material with robust material that provides significantly better wear performance	• Unknown • Potentially enable the inclusion of sample preparation module

- **D.2. Phase I Decision Point – Northrop Grumman (N.G.) "Based upon the results of Probability of Detection, the NG-ADS assays met the Gen-3 Phase I DP#1 pass/fail criteria.**
-
- **D.2. Phase I Decision Point – Hamilton-Sundstrand (H.S.) " HSSI Assay Evaluation technically did not meet DP #1 due to performance problems early in the testing.** Comment: The metric of success was that the vendor must detect at least one of the BioWatch Threat Agents at or below [redacted] per reaction with a Probability of Detection of 95%). The HSSI System passed this metric. Yet, the Contracting Officer determined that the assay evaluation results failed to meet the requirements of the Contract.

  On December 17, 2010, OHA met with Hamilton Sundstrand to discuss the decision to no longer fund them within the BioWatch Gen 3 Phase I contract. HSSI questioned OHA's decision on technical grounds. On December 30, 2010 OHA requested S&T/CBD to conduct an independent technical review of the testing data results relative to their decision.

  Based on CBD's review of the limited data set (for only one biological agent of concern) provided by OHA for analysis, CBD noted the following deficiencies in the testing and evaluation process:
  - "The bench top test system employed for assay evaluation (the High Throughput Analytical Component or HTAC) was not the technology or configuration used in the fielded system. The HTAC system uses a different thermo cycler and micro fluidics than that used in the Hamilton Sundstrand (HSSI) analytical subsystem. To the best of our knowledge, no testing was performed on the HSSI analytical subsystem to determine if the assay evaluation data and conclusions from testing of the bench-top system are comparable to detection performance of the subsystem or system."
  - "The algorithm associated with the test system does not provide accurate interpretation of results based on the data provided, which includes many instances for potential false positive detections. Based on the analysis of the limited test data provided by OHA, it appears that the system configuration (the HTAC reader) tested by OHA has inconsistencies in the algorithm and chemistry used to determine a positive detection."
  - S&T/CBD expressed its concerns to OHA in writing that: "the Hamilton Sundstrand (HSSI) assay evaluation was performed on a bench-top system that is significantly different from the analytical subsystem and system (developed by S&T) and therefore cannot make conclusive statements on the operational HSSI assay and system performance. Without testing the actual HSSI analytical subsystem, the assay evaluation data provides little value to derive any substantive conclusions as to how the system will perform as required by the BioWatch program."

In addition, the above Phase I Assay Evaluation using a subset of a PSAA panel revealed that the NG Assay had the potential to yield false positive and negative results which is a clear indication that the system failed Phase I testing.

DOCUMENT: Memorandum For the Record, Date: April 6, 2012. From: Dr. Michael Walter, Program Manager, BioWatch Program Office.

Comments:

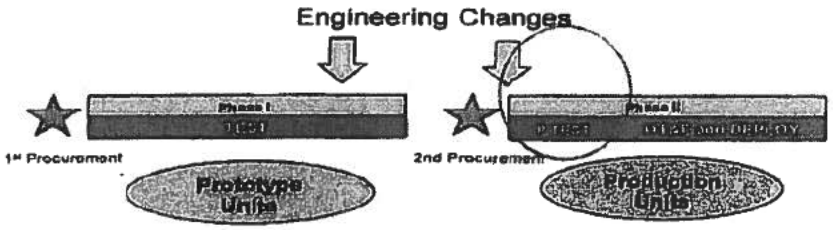
- **p.2 "Sandia National Laboratory Systems Analysis Study. "The BioWatch SPO commissioned SNL to lead a consortium of National Labs in the preparation of a performance trade-off study, examining the relative benefits of the time-to-detect system sensitivity, and number of deployed detectors related to lives saved. The resulting suggests that the System Sensitivity requirements contained in the Gen-3 ORD v.1.1 and v.2.0 were too stringent, prompting the SPO to update the System Sensitivity. As such, the BioWatch Program Office reduced the System Sensitivity threshold requirement from [redacted] (organisms/m3) to [redacted] (organisms/m3) x minutes for indoor environments and [redacted] (organisms/m3) x minutes for outdoor environments.**

  Comments: The Requirements used by OHA to update the Gen-3 ORD v 2.2 (dated January 2012) are very confusing and misleading. No information is provided as to the rationale for changing operational system sensitivity to [redacted] Also, different system sensitivities are indicated for both INDOOR and OUTDOOR systems. Will different systems with different sensitivities be developed for indoor and outdoor to meet these metrics? Why have these requirements changed from a 6 hours collection period to a 3 hours collection period and what is the benefit? The Threshold for indoors is [redacted] x minutes for bacteria and viruses. The Threshold for outdoors is [redacted] x minutes for bacteria and viruses. The document states that these are equivalent to system sensitivities of [redacted] These sensitivities are relatively low. For outdoor attacks, if the collector collects [redacted] org min/m^3), than the [redacted] If the collector requires [redacted] over 3 hours ([redacted] org min/m^3), the [redacted] (Per Sandia National Lab study) CBD advises against changing system sensitivity requirements based solely upon the candidate systems tested. The system sensitivity must be set at a level that ensures a high probability of detection (Pd). S&T recommends [redacted]

Need for Changing the Schedule

OHA PPT Slide of NG testing

- Confirmation that improvement in production units has occurred requires more detailed testing before deployment.



Comments on next page

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Comments:

OHA plans to test the NG system with modifications at the start of Phase II. It is our recommendation that the ORD for sensitivity not be changed at the current time. Given the fact that OHA has already invested significant resources to support significant changes to the existing NG system about a year ago, it is our recommendation that the system be tested against the original ORD sensitivity level of [redacted] to understand the performance based upon the engineering changes prior to making ORD changes. It should also be noted that significant engineering changes by OHA to the Northrop Grumman system do NOT mean that the system sensitivity of the technology will become any lower.

DOCUMENT: Gen-3 Automonous Detection System Operational Requirements Document v2.2 (Dated January 5, 2012)

Comments:

The most important changes to this document are found on page 3-2. The ADS system sensitivity metrics have been modified from the previous Operational Requirements Document. The August 2011 ORD requirement for system sensitivity was meeting a threshold of [redacted] and the objective of [redacted] This has now been changed for threshold of [redacted] for outdoors/indoors. The concern is that the system sensitivities are being modified to match the metrics of the Northrop Grumman system, rather than ensuring that there is high confidence in the Probability of Detection (Pd) of the technology.

DOCUMENT: Gen-3 Autonomous Detection System Test and Evaluation Master Plan v 2.1

Comments:

Page D-3: **Assay Evaluation**

"Assay Evaluation is designed to measure Gen-3 Detector assay performance in terms of sensitivity, specificity and repeatability. The test design will be based upon SPADA. The assay evaluation will use liquid samples of purified DNA processed through a high throughput bench-top version of the system's analytical subsystem to include an automated algorithm that detects and identifies the appropriate strains. The Assay evaluation will be conducted at LANL and CDC. Modifications to the assay evaluation event may be made if the assay has met all or some of the data requirements described in the Phase II RFP prior to the test event. A portion or the entire assay evaluation may not be required. Also, if the assay has met all or some of the data requirements described in the Phase II RFP, but has since received engineering changes or design modifications, than appropriate regression testing will be required. Assay evaluation regression testing will verify the performance of modified assay components to ensure no detriment to previously working functions."

Comments: This language raises questions or concerns as what is truly meant by "*modifications to the assay evaluation event will be made if the assay has met all or some of the data requirements described in the Phase II RFP. A portion or the entire assay evaluation may not be required.* No technology or system assays should get a pass from undergoing full evaluation of assays. What metrics will be used to evaluate and determine if an assay has met all or some data requirements as described in the Phase II RFP? 2. "The high-throughput bench-top version of each system's analytical subsystem will be used for system testing." Significant concerns were raised in Phase I

testing regarding the use, operation and performance of high-throughput bench top systems. As there were false positive and negative issues with the NG system it's highly recommended that if changes are made to the Assays within the Gen-3 system they must be re-tested to generate the appropriate data for subsequent evaluation to determine overall performance.

Page D-4: **Aerosol Collection Subsystem Test**
"Modifications to the aerosol collection subsystem test event may be made if the aerosol collection subsystem has met all or some of the data requirements described in Phase II RFP prior to the test event".

Comments/Questions: What is the decision making process? This is a concern, as in the Assay Evaluation above, that decision process will be used to evaluate if data requirements have been met? It is highly recommended that if changes are made to the Aerosol collection system it must be re-tested to generate the appropriate data for evaluation to determine performance.

Gen-3 Autonomous Detection System, Operational Requirements Document v 2.0, August 12, 2011, signed by Bob Ranhofer and Mike Walters (copy attached)

Comment: This document was not included in the list of IRB documents for review. The metrics were changed from the original [redacted] (in ORD v1.1) to include the objective of [redacted] This ORD Version was not provided in the documents as sent. However, it's important to note that OHA decided to modify the System sensitivity requirements to the [redacted] last year.

3.1.4 System Sensitivity
The Gen-3 ADS shall have a system-level sensitivity[4], average air concentration of agents over the collection period, equal to or less than [T]:
(a) [redacted] per cubic meter for bacteria (vegetative cells or spores)
(b) [redacted] per cubic meter for viruses

The Gen-3 ADS shall have a system-level sensitivity, average air concentration of agents over the collection period, equal to or less than [O]:
(a) [redacted] per cubic meter for bacteria (vegetative cells or spores)
(b) [redacted] per cubic meter for viruses (DNA or RNA)
(c) [redacted] per cubic meter for toxins

Document 29

Pillai, Segaran

From: Hall, Wendy
Sent: Thursday, July 12, 2012 8:25 PM
To: Drabkowski, Douglas; Pillai, Segaran
Subject: RE: GEN-3 IRT OUTBRIEF

Ah yes. But Jerry and I might not give up on that as we recommended some related items to A/S Heyman and would need to ask S&T for technical support to further our Policy thinking about Gen3 requirements that meet various biodefense policy objectives. And we have to have a more solid idea of our policy goals to be able to effectively evaluate the documents that OHA will be working to produce.

From: Drabkowski, Douglas
Sent: Thursday, July 12, 2012 1:29 PM
To: Pillai, Segaran; Hall, Wendy
Subject: FW: GEN-3 IRT OUTBRIEF

FYI – Apparently, IRT and IRB meetings postponed through the calendar year to address some of the S&T Acquisition Recommendations, but apparently not all.

Additional S&T recommendations NOT mentioned include:

1) System-level characterization of the current BioWatch Gen-2 performance.
2) Cost-benefit Analysis of the deployed Gen-2 vs the proposed Gen-3 system.
3) Evaluate if the N.G. assays have been updated to ensure greater assay sensitivity, specificity and reproducibility.
4) Independent Validation and Verification of the assumptions found in the Sandia National Laboratory models/studies.

Doug Drabkowski
Acting Deputy Director & Transition Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
[redacted]

From: Durham, Debra
Sent: Thursday, July 12, 2012 1:21 PM
To: Drabkowski, Douglas; Murata, Christina; Benda, Paul

Cc: Kerr, Gibson
Subject: RE: GEN-3 IRT OUTBRIEF

The OHA BioWatch GEN3 IRT Outbrief on 16 July, the USM Pre-Brief on 25 July, and the IRB on 3 Aug have been cancelled.

OHA will complete the CONOPS, threat analysis, and perform the Alternative Analysis before the IRB will be held sometime next calendar year.

From: Drabkowski, Douglas
Sent: Thursday, July 12, 2012 9:28 AM
To: Durham, Debra
Subject: GEN-3 IRT OUTBRIEF

Debra - Just checking to see if you or reps from your office will be attending the Gen-3 Out-Brief scheduled for Monday. Apparently the meeting is to discuss comments and recommendations from S&T and Policy. I will be attending on behalf of CBD/S&T. Doug

Subject: GEN3 IRT OUTBRIEF
When: Monday, July 16, 2012 1:00 PM-2:30 PM (GMT-05:00) Eastern Time (US & Canada).
Where: OHA BioWatch SPO - 675 N Washington St, Alexandria, VA 22314; Suite 220; Large Conf Room 200

When: Monday, July 16, 2012 1:00 PM-2:30 PM (GMT-05:00) Eastern Time (US & Canada).
Where: OHA BioWatch SPO - 675 N Washington St, Alexandria, VA 22314; Suite 220; Large Conf Room 200

Note: The GMT offset above does not reflect daylight saving time adjustments.

+~+~+~+~+~+~+~+~+~+

*** Latest IRB Date scheduled for August 3, 2012 from 1:30 to 2:30 at the NAC with S2***

ALCON:

The GEN3 IRB 2B decision meeting has been postponed to the first week in August. See above.

Meanwhile, given that the GEN3 acquisition has garnered interests and comments from S&T and Policy (see below). PARM is holding an IRT Out Brief to discuss and work out all issues pertaining to this acquisition.

Doug Drabkowski
Acting Deputy Director & Transition Branch Chief

Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
Office: 202-254-5808
Email: douglas.drabkowski@hq.dhs.gov

Document 30

Young, Loretta

From: O'Toole, Tara
Sent: Tuesday, June 19, 2012 3:03 PM
To: de Vallance, Brian
Subject: RE: Bio mtg

Dear Brian -
Thanks for the update. I don't know what the time pressures are; OHA would know better. I would like very much to be at the IRB, but am traveling 4/27 and 28 and am on vacation the week of July 4.

I think a pre-mtg session would be very good idea. This is a highly visible, controversial acquisition, one of the largest (in $ terms) in DHS, and people are watching for it - as WA Post article indicates. Also in the background is a 2010 National Academy of Sciences report requested by Cong Price (and extensively quoted by GAO).

The GAO report now circulating in DHS for accuracy check (release date in August) is highly critical of the acquisition process. There is another report on the state of the biowatch technology by HSSAI which the Secretary requested (have not seen it). S&T's written comments to the IRB express a lot of skepticism about whether the technology works and whether we are getting our money's worth. The House Approps bill does not include money for BW operational testing until the Secretary "certifies" that it is prudent to do so and provides an alternate plan (essentially an analysis of alternatives, which S&T also wants to see done).

Alex Garza, on the other hand, told me this morning that he does not regard the BioWatch Acquisition to be "high risk" and he has aggressively sought permission to proceed.
So there will be a lot of different opinions about whether and how we should go forward.
Not sure if a bigger or smaller mtg would be useful, but I think it would be useful to have a somewhat formal presentation of the "facts" and concerns from OHA, S&T (not T&E, I would present) and USM or their rep.

Alice Hill is also involved in this.

Let me know if I can help.
Tara

Tara O'Toole MD, MPH

Under Secretary for Science & Technology Department of Homeland Security

[redacted]

tara.otoole@dhs.gov

-----Original Message-----
From: de Vallance, Brian
Sent: Tuesday, June 19, 2012 2:32 PM
To: O'Toole, Tara
Cc: [redacted]
Subject: Bio mtg

Dr. O'Toole,

MGMT does recommend that we move the big Bio mtg, which we usu accommodate it approved by the U/S, which it was here. Erin will let you know when we move it to. 2 Qs for you:

1. I assume we consider this time sensitive for reasons that we discussed, so we need to resched it asap, correct? If so, we will do it as soon as MGMT can.

2. Do you recommend a separate (short) prep session for the larger mtg?

3. If so, who should attend the prep session?

Thx.

Brian

Document 31

Young, Loretta

From: O'Connor, Erin
Sent: Monday, June 25, 2012 7:35 PM
To: O'Toole, Tara
Cc: [redacted]
Subject: RE: BioWatch IRB

FYI

S2 met w/Huban and Alex and Amy Shlossman.

No larger meeting being scheduled at this time.

From: O'Toole, Tara
Sent: Tuesday, June 19, 2012 2:49 PM
To: O'Connor, Erin
Subject: RE: BioWatch IRB

I have had it on my calendar as a S2 mtg for about a month, but the mtg may have been called by USM.

It's up to the Deputy, but I think a prep session would be excellent idea.
This is highly complex acquisition -- both because the technology is complex and hard to understand, and because of the unusual history of the program. It is a multi billion dollar deal.
Moreover, this is highly visible and controversial acquisition with story in yesterday's WA Post and no money for acquisition in OHA's House budget.
I think S&T and OHA have conflicting views of the program. Not sure what USM thinks.
I would really like to be at the IRB but am traveling 2 days next week and off the week of July 4.

Call if I can help.

Tara O'Toole MD, MPH

Under Secretary for Science & Technology
Department of Homeland Security
[redacted]

tara.otoole@dhs.gov

From: O'Connor, Erin
Sent: Tuesday, June 19, 2012 2:00 PM
To: O'Toole, Tara
Cc: Gifford, Ashley; Young, Loretta
Subject: BioWatch IRB

Dr. O'Toole:

Brian just said you were asking about a prep for BioWatch DC.

We didn't have a prep session on. Do you want a prep? If so, I'll ask S2.

Separately, IRB folks in MGMT JUST asked me to cancel and MOVE the BioWatch IRB.

Erin O'Connor
Office of the Deputy Secretary
Department of Homeland Security
Email: erin.oconnor@hq.dhs.gov
[redacted]

Document 32

Pillai, Segaran

From: Drabkowski, Douglas
Sent: Monday, August 06, 2012 11:38 AM
To: Pillai, Segaran
Subject: FW: BioWatch Gen-2 Data

Dr. Pillai - Please see below my follow-up emails to Mike Walters of OHA regarding our request for information specific to the current Gen-2 system. As of this date we have not received a response from OHA. Thanks. Doug

Doug Drabkowski
Acting Deputy Director & Transition Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
[redacted]
Email: douglas.drabkowski@hq.dhs.gov

From: Drabkowski, Douglas
Sent: Friday, January 20, 2012 12:11 PM
To: Walter, Michael; 'Hooks, Robert'
Cc: Gerstein, Daniel; Pillai, Segaran; Ranhofer, Robert; Johns, Malcolm; 'jerome.holton@taurigroup.com'
Subject: RE: BioWatch Gen-2 Data

Thanks Mike!

In general we are trying to understand the current Gen-2 system sensitivity in order to better inform robust biomonitoring systems of the future.

As such, it would be most helpful to receive information on the following:

1. Available data that informs the current (Gen-2) system sensitivity.
2. Whether or not Dugway chamber testing was performed to understand current (Gen-2) system sensitivity for the five (or six) BioWatch agents.
3. What the current sample processing efficiency is for the five (or six) BioWatch agents.

Thanks in advance for your responses to these items. Regards -

From: Drabkowski, Douglas
Sent: Friday, January 13, 2012 4:40 PM
To: 'Hooks, Robert'; Walter, Michael
Cc: Gerstein, Daniel; Pillai, Segaran
Subject: BioWatch Gen-2 Data

Bob and Mike –

It was great having a meeting yesterday to discuss the merits of Fp and Pd in the context of BioWatch detecting biological releases that impact significant numbers of people.

During the meeting, you provided an affirmative response to Paul Benda's question regarding availability of test data for the performance of the current BioWatch Gen-2 system (PSUs and lab extraction procedures). It would be appreciated if you can forward such data back to my attention within the next week.

Thanks much for your assistance in this matter.

Sincere regards -

Doug Drabkowski
Acting Deputy Director
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
[redacted]
Email: douglas.drabkowski@dhs.gov

Document 33

U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

SEP 0 7 2012

ACQUISITION DECISION MEMORANDUM

MEMORANDUM FOR: Dr. Alexander Garza
Assistant Secretary for Health Affairs

FROM: Rafael Borras
Under Secretary for Management

SUBJECT: Bio-Watch Generation-3 Acquisition

A Department of Homeland Security (DHS) Acquisition Review Board (ARB) review of the Office of Health Affairs (OHA) Bio-Watch Generation-3 (Gen-3) Program, chaired by the Under Secretary for Management, was held on August 16, 2012. This ARB was a program review to determine the program's feasibility to approve the revised 2-Stage Acquisition Strategy and release the Gen-3 Phase II Stage 1 Request for Proposal (RFP) for performance testing.

The Bio-Watch Gen-3 Program has been working since August 2011 to develop a viable alternate 2-Stage Acquisition Strategy to mitigate programmatic and technical risk for Phase II in preparation for an Acquisition Decision Event (ADE) 2B milestone. The program has responded to all of the action items assigned in the June 2010, December 2010, and June 2011 Acquisition Decision Memorandums (ADMs). The program presented an alternative approach to reduce programmatic and technical risk based on the previous Phase I Gen-3 test results and the original acquisition strategy. The Bio-Watch Program has submitted ADE 2B acquisition documentation based on the multi-vendor acquisition strategy for DHS review. These efforts demonstrate significant progress in the Bio-Watch program's maturity and compliance of Management Directive (MD) 102-01. The program's lack of maturity and MD 102-1 compliance were cited as significant risk within the February 7, 2012. However, it was noted by the ARB that the program must update the Acquisition Program Baseline (APB) and associated documentation to reflect the change in the acquisition strategy.

During the Bio-Watch Program's Gen-3 Phase II acquisition planning, the Government Accountability Office (GAO) performed a program audit, and DHS commissioned an independent study by the Homeland Security Studies and Analysis Institute (HSSAI) to determine how to decrease the program risk. Both of these efforts concluded in July 2012. The draft recommendations of GAO and the HSSAI Study recommended that the Bio-Watch Program conduct additional Analysis of Alternatives (AoA) before the Gen-3 acquisition proceeds. HSSAI further recommended the program update the Concept of Operations (CONOPS) to ensure Gen-3 requirements adequately address "the full operational landscape." It further recommended that the program update other acquisition documentation to reflect the AoA and CONOPS.

Based on these two separate activities, the program proposed a parallel path of conducting Gen-3 performance testing of ten units from each competitively selected vendor, while conducting the AoA and developing a CONOPS. The ARB had a productive discussion with the program about the benefits and risks of adopting this approach. The Acquisition Decision Authority gave contingent approval for the Bio-Watch Program to prepare two solicitations: 1) conduct an AoA and 2) conduct Gen-3 Stage 1 performance testing, based on the current Operational Requirements Document (ORD). Approval to release the RFPs is based on completion and ARB review and approval of the following tasks:

- Acquisition Plan: Must reflect the updated strategy and be approved by the Head of Contracting Activity and Chief Procurement Officer before the Gen-3 performance testing solicitation can be released.

- Integrated Master Schedule: Within two weeks of the ARB (August 30, 2012), the Bio-Watch Program is required to provide a Gen-3 Integrated Master Schedule reflecting the revised acquisition strategy and including stakeholder inputs and activities (i.e., all government, including Science and Technology Directorate and Office of Health Affairs (OHA) activities).

Before Gen-3 Stage 1 performance testing contract award(s) the Bio-Watch Program must return to an ARB. To support that ARB, the following actions must be completed and provided for review and approval no later than 45 days prior to the planned contract award date:

- AoA and CONOPS: The AoA must include a Cost-Benefit Analysis of the deployed Bio-Watch Gen-2 performance versus the proposed Gen-3 performance. The AoA must consider the current operational system, as an alternative approach, including a Threat Clarification Analysis to establish a basis for the recommended alternatives. The Bio-Watch Program must also complete a CONOPS that explains how bio-detection technology will be used in each type of environment required under this program and the role of state and local jurisdictions.

- Other Acquisition Document: The Bio-Watch Program must revise all other acquisition and systems engineering support documents (e.g. Acquisition Program Baseline (APB), Life Cycle Cost Estimate (LCCE), Operational Requirements Document (ORD), Test and Evaluation Master Plan (TEMP), and the Systems Engineering Life Cycle Project Tailoring Plan (SELC TP) as appropriate based on the AoA, CONOPS, and the revised 2-Stage Acquisition Strategy.

It is the responsibility of both the OHA and the Bio-Watch Program Office to ensure results of this ADM are promulgated to the affected organizations. The Office of Program Accountability and Risk Management (PARM) will provide support and assistance as needed. Please send action items, status, and supporting documentation to PARM@hq.dhs.gov. Should you have any questions, please contact Brian Chu at [redacted] or Brian.Chu@hq.dhs.gov.

cc:
Deputy Secretary
Under Secretary for Management
Deputy Under Secretary for Management
Chief of Staff, Under Secretary for Management
Assistant Secretary for Policy
Deputy General Counsel
Chief Administrative Officer
Chief Human Capital Officer
Chief Security Officer
Chief Financial Officer
Chief Procurement Officer
Chief Information Officer
Executive Director, Office of Program Accountability and Risk Management
S&T, Director, Operational Test & Evaluation
S&T, Systems Engineering Directorate
Chief Financial Officer, OHA
Chief Information Officer, OHA
Component Acquisition Executive, OHA
Program Manager, OHA Bio-Watch GEN-3 Program

Document 34

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Sunday, May 22, 2011 4:01 PM
To: Bell, Beth (CDC/OID/NCEZID); [redacted]
Subject: OPR on LRN - draft outline of presentation

Beth [redacted]

Here (below and attached) is the outline of my QPR presentation on LRN. I would like to be able to go over this with you on Monday. I am most concerned about what I should say about the challenges.

Thanks,

Toby

"Assuring the United States Can Detect and Respond to Infectious Diseases – The Role of the Laboratory Response Network (LRN).

Background:

- The Laboratory Response Network (LRN) is a system of laboratories providing rapid, highly reliable testing and expertise for biological and chemical agents regarded as threats to the public health.
  - Hallmarks of LRN are:
    - Ready availability
    - State of the art science
    - Rapid testing
    - High precision and accuracy of the testing
    - Highly standardized assays and highly trained personnel
    - Ready availability of expertise to assist with interpretation of results.
- There are 170 LRN laboratories providing testing for biological agents, including (and I am going to confine my discussion today to this biologic testing):
  - Within the US: local, State, and federal civilian and Department of Defense (DoDl laboratories
  - Outside the US: Mexico and Canada, as well as DoD facilities
- LRN is organized and funded largely by the CDC, but is managed in collaboration with APHL and the participating laboratories.
  - CDC Preparedness funds come to NCEZID to develop, maintain, and support the program and laboratory assays
  - CDC Preparedness funds go to the States and some cities through the Public Health Emergency Preparedness (PHEP) funds to support the State and local participating laboratories.
  - DHS funds come to NCEZID to support assay development.

Recent Successes:

- LRN in States and some cities (and DoD) were rapidly able to perform testing for 2009 H1N1 on RT-PCR instruments deployed in LRN.
  - 2009 H1N1 pandemic demonstrated value in having distributed network of state of the art diagnostic laboratories
  - Probably over 90% testing for 2009 H1N1 Influenza was performed in LRN laboratories in the States and some cities.
  - LRN has dramatically improved public health laboratory infrastructure nationwide

- Improving collaboration with FDA
  - Working with FDA on regulatory pathway for LRN assays
  - FDA has agreed to need to change in methods (absolute quantity of DNA rather than colony forming units) as limits of detection standard for RT-PCR assays
- Mexico LRN is up and running
  - Major obstacle has been shipping and receiving of materials – import and export permits, customs issues
- LRN has forged new, improved relationships between State and local public health laboratories and the clinical diagnostic community
  - According to APHL

Challenges:

- Funding
  - LRN vulnerable to decreases in Preparedness funding, especially because of collaborative nature of LRN.
    - PHEP funds to States now decreased for 2011
    - PHEP funds likely to decrease further in 2012
    - PHEP funds to States do not go directly to laboratories and there is no funding specifically for LRN.
    - Preparedness funds to NCEZID proposed to decrease in 2012
- Biowatch
  - DHS-run program to sample outdoor and indoor air in multiple cities
  - LRN and CDC must be able to understand and verify Biowatch results in order to be able to assist in decisions about appropriate public health action
  - Requires substantial CDC resources to perform this function
  - Is planning to implement new Biowatch testing technology (Gen 3) with more sampling, in more locations.
    - CDC has concerns about technology; failure to target/meet standards for public health actionable assay
    - CDC has concerns about impact of demands of increased testing on LRN
  - Biowatch program is unpopular is questioned in some quarters, including parts of DHS.
- Adding international laboratories
  - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations.

QPR on LRN
052511 TMdraft...

Presentation to CDC Director
NCEZID Quarterly Performance Review
May 225, 2011

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    - CDC has concerns about technology; failure to target/meet standards for public health actionable assay
    - CDC has concerns about impact of demands of increased testing on LRN
  - Biowatch program is unpopular is questioned in some quarters, including parts of DHS.
- Adding international laboratories
  - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations.

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 25, 2011 5:04 AM
To: Bell, Beth (CDC/OID/NCEZID); [redacted]
Subject: Almost best-and-final version of QPR presentation on LRN

Beth [redacted]

I was not able to send this out electronically yesterday afternoon and evening, because of a problem with Outlook. I gave Beth a hard copy, and the only substantive change since then is adding a discussion of "specimen surge" to the challenges.

Please let me know any suggestions or concerns you have.

Thanks,

Toby

QPR on LRN 052511 TM.docx

Presentation to CDC Director
NCEZID Quarterly Performance Review
May 25, 2011

"Assuring the United States Can Detect and Respond to Infectious Diseases – The Role of the Laboratory Response Network (LRN).

Background:

- The Laboratory Response Network (LRN) is a system that enables participating States, cities, federal agencies, and international partners to provide rapid, highly reliable laboratory testing for biological and chemical agents regarded as threats to the public health.

- I am going to speak today primarily about the biological side of LRN, which is 1) the largest operating component of LRN, 2) the foundation of LRN, and 3) supported by multiple Divisions in NCEZID.

- LRN facilities have the state-of-the-art equipment, personnel, training, reagents, procedures, information systems, quality assurance program, and the connection to subject matter experts that enables these facilities to produce and report laboratory results that are highly reliable and appropriate for public health actions.

- There are 165 total LRN laboratories: 115 State and local health department; 19 federal agency (FDA, NIH, CDC); 7 veterinary; 11 military (including South Korea); 13 international (Canada, UK, Australia, and [very soon] Mexico); and 3 higher level national facilities including CDC, USAMRID, and Naval Medical Research Center.

- Standardized testing and reporting across all of these laboratories minimizes methodological variation and assures that a result from one laboratory is equivalent to a result from any other laboratory.

[redacted]

- CDC develops, produces, and distributes the tests and supplies the individual LRN laboratories with the test kits, policies and procedures, training, quality assurance, information systems (LRN-messenger), and supporting subject matter expertise.

- LRN is funded largely by the CDC from Preparedness funds. The intramural activities at CDC are funded by "Upgrading CDC Capacity funds" which NCEZID receives from PHPR. CDC also receives some funds from DHS for assay development. The State and local LRN laboratories are funded through the Public Health Emergency Preparedness grants from PHPR.

- The LRN equipment and personnel are so-called "dual use" resources and are used to support other State and local laboratory activities [redacted]

- APHL serves a critical role in facilitating the participation of State and local laboratories in LRN

Recent Successes:

- A substantial proportion of the testing for 2009 H1N1 influenza performed in States and cities (and DoD) was possible because of the LRN.
    - LRN laboratories served as the "warm base" for 2009 H1N1 test kits developed and distributed by CDC.
    - Equipment and personnel trained and experienced in real time PCR were readily available, and the LRN laboratories in the States and cities had worked on a predecessor influenza assay.
    - Proof of the public health value of "dual use" of standard testing platforms.
- In the past 2 years, CDC's collaboration with FDA on LRN has substantially improved.
    - CDC is working with FDA on mutually acceptable a mutually acceptable regulatory pathway for LRN assays.
    - FDA has agreed to need to change in methods (absolute quantity of DNA rather than colony forming units) for measuring sensitivity and specificity of PCR for detection of microorganism.

- Mexico LRN is almost up and running
    - Major obstacle has been shipping and receiving of materials – import and export permits, customs issues.
    - The remaining step is training now scheduled for late summer
- CDC is improving its PCR assays for biothreat agents.

[redacted]

    - We plan to change the cycling time threshold for the assays which will decrease the number of non-verifiable positive results for Ft.

Challenges:

- Decreased Preparedness funding is impacting LRN
    - Within CDC, we are critically examining how we spend dollars on assay development and deployment. Our first priority is improvement of assays for our existing menu of targets.
    - Compliance with FDA regulations will have a cost.
    - For the LRN laboratories in the States and cities, decreased PHEP funding will have an impact.
        - We are committed to maintaining the quality of LRN testing and reporting as the backbone of LRN.
        - We will be working with APHL and our State and local partners to look at strategies for operating LRN in this environment.
        - (I may not say this) The elephant in the room is the question about how many LRN laboratories do we need in the States and cities.
- The Biowatch continues to be a major challenge to LRN.

[redacted]

    - CDC currently supplies kits for the PCR testing of these environmental samples. CDC serving as the source for the assays may change in the near future, but this change will not address the fundamental challenge.
    - The fundamental challenge that testing large numbers of low probability environmental specimens for these agents inevitably generates occasional positive PCR result. CDC and LRN must be able to

understand and be able to verify Biowatch results in order to be able to assist in decisions about appropriate public health action.

- The Biowatch program is now developing new technology (which they call Gen 3), and CDC has concerns about this new technology, which we are actively discussing with DHS. Concerns about:
  - Sensitivity and specificities of the assays.
  - Claims that the new technology generates "confirmed" results.
  - Potential workload impact on LRN from increased number of devices that are continuously sampling and reporting.
- Biowatch program is unpopular is questioned in some quarters, including parts of DHS.

- Adding international laboratories
  - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations.

- Planning and exercising for specimen surge
  - Some types of events could produce a dramatic increased demand for LRN testing, particularly of environmental specimens
  - How to manage this surge requires scenario planning and exercising that needs to occur.
  - Space and logistics for surge testing is a basic problem that we need to address.

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NCEZID Quarterly Performance Review
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- Standardized testing and reporting across all of these laboratories minimizes methodological variation and assures that a result from one laboratory is equivalent to a result from any other laboratory.

- Individual State and local laboratories choose the tests that they perform based on their individual needs. [redacted]

- CDC develops, produces, and distributes the tests and supplies the individual LRN laboratories with the test kits, policies and procedures, training, quality

assurance, information systems (LRN-messenger), and supporting subject matter expertise.

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    - Claims that the new technology generates "confirmed" results.
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- Adding international laboratories

    - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations.

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    - How to manage this surge requires scenario planning and exercising that needs to occur.
    - Space and logistics for surge testing is a basic problem that we need to address.

Document 35

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Thursday, May 26, 2011 8:12 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: FW: I'm going to have another private conversation tomorrow with Mike Walter and [redacted]


Information: BioWatch Gen-3


RE: INFO: ...Multiplex informati...


INFO: Multiplex information f...

Hi Toby, in addition to what I sent you last night, here are some additional e-mails providing information on panels 3 and 4. If you want to look at the spreadsheets, I will send the passwords in a follow on e-mail.

Thanks, Mike.

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Thursday, May 26, 2011 12:15 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: I'm going to have another private conversation tomorrow with Mike Walter and Ulana Bodnar

Hi Dr. Merlin, here are some specifics:

We have not seen the results of the SPADA assay validation studies that are finished and the report from DHS is pending.

DHS S&T and the CDC would be much happier if these assays underwent the intense PHAA standards that we are currently pursuing in that they would be the best that they could be from a confidence standpoint for supporting public health decisions.

The CDC was specifically told on more than one occasion that the two vendors competing for the Gen 3 procurement were developing their own assays PCR detection assays because for legal reasons they could not be provided with government-developed assays. We have since found out that this is not true and DHS claims also to not have known.

There were a few different iterations of the assay panels of the APDS system that was field tested in NYC. That system experienced problems and was ultimately pulled with the 3rd panel version of the assays. The fourth version was under development at that time and that is the panel that is now incorporated into the Gen 3 system. Following the demise of the APDS, side by side testing of the APDS and LRN Ba assays showed the APDS assay/chemistry to be 100 fold less sensitive that the LRN assay/chemistry. Same assay, different platforms and chemistries.

Of the 19 Gen 3 panel assays, 13 are current LRN assays and 2 others are the additional VRL3 and VRL 4 signatures that the BioWatch program uses. Inger Damon knows that these assays cross react with various other pox viruses and also knows that these assays experience specificity challenges in the

context of the Luminex multiplexed chemistry. Inger received funding from DHS through an IAA to evaluate the Gen 3 assays, when they were revealed to her and she realized they were the current LRN/BioWatch signatures she did not want to waste time evaluating them because she already knew that they cross react with other pox viruses which is why she is currently working hard to replace VRL1 and VRL2. She is so concerned that they are using these assays in the Gen 3 that she talked to CDC leadership about pulling out of the IAA.

Two of our three [redacted] assays and all of the [redacted] assays are in the Gen 3 system. Jeannine Petersen has demonstrated that all the [redacted] assays cross react with novicida-like environmental organisms. We see a huge amount of environmental cross reactivity in these assays all over the U.S., but in particular for places like Houston. There is an additional [redacted] assay in the Gen 3 system from LLNL. I do not know anything about this assay or its performance characteristics. I also do not know what algorithms will be applied to the Gen 3 assays to determine a positive detection.

Recent experience has caused us to strongly suspect that environmental cross reactivity is happening with the [redacted] assays, although we have not been able to definitively demonstrate this. It is important to note that NYC is currently not testing BioWatch extracts for [redacted] as they have no confidence in the LRN [redacted] assays because of the "false positives" which operationally they have no tolerance for. There is no reason to think they would have increased confidence in these assays in a different platform/chemistry.

Nine of these LRN/BioWatch signatures have the probes reversed (bind to the other DNA strand) from their original design. No specific data has been put forth to justify this change and it is not clear that this change does not alter assay performance characteristics.

I think DHS will and possibly rightly, point to changes they have made in the assays, algorithms, engineering, etc. and the successful robust systems testing and even the successful Chicago field test as justification for continuing down this road.

Bottom line for me is that despite whatever changes they have done, or assay and systems validation that they perform, the Gen 3 system with these assays is going to be dead on arrival at the Public Health Labs, especially and importantly at NYC. This will be simply because of a lack of confidence due to previous experience with environmental cross reactivity and the problematic APDS deployment. Confidence in the system is going to be paramount with the current "actionable" nature of the signal that is intended. I just don't see how this is going to be possible.

At the end of the day, if the Gen 3 system goes forward as is and fails it will be a lot of wasted money (billions) and I worry that the CDC (us) might be seen as partially responsible because we knew what was going on.

It could fail simply be being rejected by the Public Health Labs, particularly by an important jurisdiction like NYC. It is interesting that they requested (according to Pillai) that DHS S&T brief NYC stakeholders on why the APDS system failed in parallel with Scott Hughes asking some very pointed questions in Chicago about the parallels between the APDS system and Gen 3.

Please don't hesitate to call me if you want to discuss anything in detail.

Thanks, Mike

[redacted]

Document 36

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, June 24, 2011 9:16 AM
To: Farrell, Michael (CDC/OID/NCEZID); Kellogg, Richard (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: FW: 06-23-2011 Incident Notice - BioWatch Notification - F. tularensis, Houston, TX - CLOSED

I understand the disposition of this, but it illustrates to me the squishy definition of a BAR. What is the action here? Who has made the final determination of the action to take? What is that determination? It's obviously not urgent, but I would like to discuss. There seem to be different definitions of a BAR, according to the jurisdiction (e.g. NYC versus Houston).
Toby

[redacted]

Document 37

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 2:04 PM
To: Kellogg, Richard (CDC/OID/NCEZID)
Cc: [redacted] (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Subject: RE: LRN Comment on Proposed email to Ranhofer about Biowatch Gen3 signature concern

Richard,

Thanks very much for your summary. This is very helpful. We had an initial discussion with Joe Foster while you were out. What is driving this forward now is the question of continued participation in the Gen3 development, pending resolution of this issue.

Thanks,

Toby

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 1:54 PM
To: Merlin, Toby (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Cc: [redacted]
Subject: RE: LRN Comment on Proposed email to Ranhofer about Biowatch Gen3 signature concern

Toby—Although I do not know Dr. Ranhofer, this matter ostensibly relates to the Gen 3 autonomous bio-monitoring system and anticipated deployment by DHS OHA for BioWatch. At issue is the breech in informational security that I alluded to in the most recent PHAA briefing to DPEI and NCEZID and which from a due diligence perspective would warrant implementation of tighter informational security policies associated with sensitive CDC and LRN information.

Although Inger and Mike may have more detailed information, it appears that sensitive information that may have been shared with LLNL (and which should have at least been controlled by Non Disclosure Agreements to protect intellectual property and sensitive national security information related to detection of biological threat agents) was "tossed over the fence" (i.e. unauthorized transfer with no strings attached) to a commercial platform developer (Northrop Grumman). How this transpired is a conundrum to me since all previous work we have done with LLNL for these type of projects (e.g. BioNet Study) was protected by highly structured and signed NDAs as standard practice.

Beyond the aforementioned legal/informational security issue is the concern that the sequence information that NG now has is likely not the best technical information to support the efficacy of validation (specificity and sensitivity) for some of the high consequence infectious threat agents which the Gen 3 system is supposed to detect in bio-monitoring of the largest populations centers in the US. I believe you can imagine the consequences of the potential false positive testing results that Inger mentions below.

We (LRN) have not pursued resolution more aggressively due to problems with ascertaining the facts on how this series of events transpired and given that some of the other information may have been under derivative classification from the original sources (hence potential legal prosecutions for violation). Also, given lesser situations in the past, there is the potential prospect of needing to involve the FBI.

I believe Inger has outlined what is needed for going forward. We need to understand exactly what transpired that resulted in the current situation and then take actions to institute better informational security/intellectual property protections as well as remediate the known likelihood for generating false positive results in the BioWatch Program (to which CDC is currently a principal partner).

Richard

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 12:52 PM
To: Holmes, Harvey T. (CDC/OID/NCEZID); Kellogg, Richard (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Cc: [redacted]
Subject: RE: Proposed email to Ranhofer about Biowatch Gen3 signature concern

Harvey, Richard, and Mike – I forgot to copy you just now on this email. Please read and advise.
Thx,
Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 12:43 PM
To: [redacted]
Cc:
Subject: RE: Proposed email to Ranhofer about Biowatch Gen3 signature concern

[redacted]

Thanks for drafting this. I just got back to my office from the PHPR retreat. I don't know Dr. Rahnofer, but I would be happy to send this. Since the issue extends beyond variola, we might want it to come from either Joe Foster or me, though. I'm copying Harvey, Richard, and Mike for their awareness and comments.

Thanks,
Toby

[redacted]

Document 38

[redacted]

From: Holmes, Harvey T. (CDC/OID/NCEZID)
Sent: Wednesday, August 10, 2011 1:53 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Chaitram, Jasmine (CDC/OID/NCEZID); [redacted]
Subject: FW: Multiplex

For awareness...as the saga continues.

Harvey

From: Holmes, Harvey T. (CDC/OID/NCEZID)
Sent: Wednesday, August 10, 2011 1:51 PM
To: [redacted]
Cc:
Subject: RE: Multiplex

[redacted]

I believe that's the point....our conversations with DHS leadership on September 11, 2008 during our VTC revealed the fact that CDC leadership did NOT accept or approve Multiplex Panel 1/ Panel 2 equivalency, see summary of VTC below.

And in fact, during that VTC teleconference.... CDC politely 'agreed to disagree' with DHS' position that the data was equivalent.

As a reminder, the VTC was scheduled because of comments made by CDC leadership during BioWatch National Meeting in Philadelphia.....emphasizing that multiplex performance data had not been reviewed or seen by CDC and that CDC disagreed with DHS's statement that we had approved it.

Harvey

From: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Sent: Friday, September 12, 2008 9:51 AM
To: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Subject: Highlights of BW Multiplex VTC...Additional Thoughts

Additional thoughts:

- Senior-level DHS personnel became aware/discovered that DBPR leadership did NOT accept or approval Multiplex Panel 1/Panel 2 Equivalency.
- It was then revealed that Dr Meyer had accepted them.
- It was clearly stated that Dr Meyer was not authorized to accept/approve such decisions but that authority resides within the BRRAT Lab
- The reason BW Program is in its current situation.....is bcs CDC/DBPR/SME have not been involved in the decision process for selecting Panel 2, Panel 3 or the acceptance of APDS.
- DHS leadership have made key multiplex panel-selection decisions based on misinformation/mis-placed authority w/o the approval or authorization of DBPR's leadership
- DHS has chosen not to directly engage with DBPR's leadership related to Panel 2 and 3 selection.

From: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Sent: Thursday, September 11, 2008 1:56 PM

To: [redacted]
Cc:

Subject: Highlights of BW Multiplex VTC...

Lisa,

- Panel 3 will continue to be used with any signal/signature requiring WET REAGENT verification
- WET REAGENT verification is a 'short-fix' while Panel 3 undergoes a 'fast-track' validation process.
- Expansion of Multiplex is on hold, until Panel 3 validation is completed
- I agreed to serve as CDC/POC to assist Dr Pillai (and LLNL) in defining the performance data needed to meet CDC's approval....an experimental design is expected in a week.
- Dr Bowen and I focused on the lack of performance data for Panel 3 and that we were not comfortable, from a data-driven decision process, to endorse the deployment of Panel 3.
- This opinion was not shared by the majority, if not any, DHS participants.
- Indeed, when asked whether anyone would discontinue the use of Panel 3...CDC was the only voice saying 'yes'
- ...
- A solution/proposal to move forward with the current BioWatch Multiplex situation will be sent directly to you for consideration and approval by CDC leadership.
- Again, my overall sense was that CDC's perspective was not shared by most of participants.

Segaran,
I'll give you a call tomorrow to move forward with an experimental design....

Bob,
Lisa will be out of the office most of next week, if you could include Sherrie Bruce, Mike Bowen, and me on the solution/proposal

Respectfully,
Harvey

From: [redacted]
Sent: Wednesday, August 10, 2011 12:14 PM
To: [redacted]
Cc: [redacted]; Holmes, Harvey T. (CDC/OID/NCEZID); [redacted]
Subject: RE: Multiplex

Dr. Bowen, Thank you again for your response. I just need to clarify one point. Do you have anything in the files that documents (an email or a decision memo)that Dr. Meyer approved on behalf of the CDC, assay panel 1 and panel 2 as equivalent for **Multiplex/Bioplex** in **2007**? I ask that because my files indicate that Dr. Meyer was relieved as the BRATT Director in **Oct of 2006**. That would indicate that he **did NOT** have the authority to make that approval. Please provide confirmation if at all possible that Dr. Meyer did leave the BRATT Director's job in **Oct 2006**. I have the Email/Memo authored by Dr. Rotz that lays out exactly what Dr. Meyer's role and authority was as a detailee from the CDC to DHS, but it was written in **Oct of 2007**. I am looking for definitive prove that the CDC did make the approval of panel 1 and panel 2 as equivalent with a date so that it can be shown that when Dr. Meyer made that decision he did or did not have the authority to make such a decision. It all depends on when he (Meyer) left the CDC as the BRATT Director and if any documentation exists that the CDC ever approved panel1 and 2 as equivalent. .

Thank you so much for your continued cooperation and patience ,

From: [redacted]
Sent: Thursday, August 04, 2011 1:14 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Multiplex

[redacted]

Panel 1 was never deployed. Panel 2 was the first panel used in the field. The BRRAT Lab has electronic records with all the panel 1 test data. I no longer have access to these records. As I recall, panel 1 was tested extensively at CDC but there were some deficiencies in the validation of poxvirus and Burkholderia signatures.

The attached file contains a presentation made by DHS/LLNL during a CDC/DHS teleconference held on Sept. 1, 2008. Page 4 contains an assay development timeline.

During the teleconference, it was revealed that the 2007 decision by CDC to accept panel 1 and panel 2 as equivalent was made by Dr. Meyer.

[redacted]

From: [redacted]
Sent: Thursday, July 28, 2011 2:45 PM
To: [redacted]
Cc: [redacted]
Subject: Multiplex

Dr. [redacted]
Dr.
Dr.

Good Afternoon All!

Just to refresh everyone's memory, I, [redacted] (DHS- Office of the Chief Security Officer) and [redacted] (Deputy Chief, Internal Security and Investigations Division)are completing the investigation into the development, deployment and eventual stand down of Multiplex/Bioplex and APDS Gen 2.5 .

For a long time now the investigation has continued under the belief that the initial panel (Panel 1) for the Multiplex/Bioplex was initially co-developed at the CDC by the CDC (Rich Meyer and LLNL) and was validated and approved. The problems began when all the changes were made to panel 1 thus becoming panel 2 and eventually panel 3. I am learning now that even panel 1 had problems and was **not** validated by the CDC for deployment/use.

I would greatly appreciate if any of you can remember the processes involved here and provide any information as it relates to Panel 1 being approved or not. Of course, documentation that would substantiate that panel 1 was approved or not for use and/ or any documentation/communications between the CDC, LLNL and DHS as it relates to the Multiplex/Bioplex assay panels being validate/approved by the CDC would be a huge help. If the panels were not

validated and/ or approved by the CDC any documentation or communications between the CDC and DHS advising that status would be a huge benefit in the investigation.

Thank you all very much for your patience, understanding and continued cooperation in this endeavor,

[redacted]

Document 39

[redacted]

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:23 PM
To: Sosin, Dan (CDC/OPHPR/OD); [redacted]; Merlin, Toby (CDC/OID/NCEZID)
Cc: [redacted]
Subject: RE: Feedback on Tara O'Toole Discussion

Dan—you raise a number of issues that likely require more detailed discussion but my initial feedback is:

Item #1—When FDA reviewed the stringency and process for PHAA assay development their conclusion (setting GMP instrument issue aside) was that it would lead to 510k clearance for IVD medical device use.
Item #2—Current dilemma with OHA BioWatch is that they currently want to use the PSAA standard to qualify their assays for pulling Public Health level action triggers. PSAA (SPADA via AOAC contracts) was meant to provide a test qualification standard for screening assays used by traditional first responders.
Item #3—The NIST issue has some prior (forgotten history) on how the policy path was decided by DHS. There is not actually a hard requirement to use the SPADA type process. There are actually exemptions, which include exigencies associated with preparedness and response, that DHS decided not to take. Joel Ackelsburg (NYC)and I made this clear to them back in the day. The "pay to play" model that they developed has been an acknowledged failure relative to sustainment with the assay developers for the first responder community. I especially know this from my last two years of work on (and report from) the interagency Hand Held Assay WG with Bert Coursey (at DHS from NIST) and Matt Davenport (at DHS and funding SPADA with AOAC contractor).
Richard

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Friday, September 09, 2011 11:40 AM
To: Kellogg, Richard (CDC/OID/NCEZID); [redacted]; Merlin, Toby (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Tara O'Toole

I bumped into Tara while visiting DHS yesterday and we rode up the elevator together. I took the opportunity to put in a good word for Pillai and our work with him and Tara jumped right into the PHAA/BioWatch issue (I rode to her floor for a bit more time to talk!).

Tara asks good questions and wants to do the right things here, but also wants our support, particularly in communicating with Alex Garza and OHA if we think PHAA is the right standard.

1. I shared support for the PHAA model developed over multiple years of deliberation and she asked if it was "too rigorous". I find it hard to believe that when it comes to taking actions involving human life we can be too rigorous, the cost balance does seem to be an issue. In addition to being sure ourselves that this is the right standard, we might want to consider getting support elsewhere. FDA commented on the process, I believe, but don't recall how that endorsement came out.
2. I shared that DPEI had some success at the BW meeting addressing concerns about the Gen3 process, but was not definitive on what that understanding was. It seemed that before the BW meeting that there was discussion about the Gen3 conops changed to not being public health actionable. It would help to clarify that point. Even though the need to meet with Alex on this particular point was addressed, it is clear that Tara feels her program would benefit our ongoing engagement with him to support their work.
3. The monkey wrench about NIST or other national standards organizations seems to still be an issue. Tara indicates that NIST is hugely expensive and nobody wants to pay for that. Without it, we will need to address

why we think PHAA is different (and does not require blessing of a national standards organization) and why this is the right standard for this high consequence application.

It might be good to follow up with Pillai to be clear what S&T wants/needs from us to keep this methodology in play.

Thanks,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333
[redacted]

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Document 40

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:36 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Subject: RE: Feedback on Tara O'Toole Discussion

Dan,

I think this warrants another 1:1 meeting of just you and me. I will look at the calendar and schedule.
Thanks,

Toby

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:23 PM
To: Sosin, Dan (CDC/OPHPR/OD); [redacted] Merlin, Toby (CDC/OID/NCEZID)
Cc [redacted]
Subject: RE: Feedback on Tara O'Toole Discussion

Dan—you raise a number of issues that likely require more detailed discussion but my initial feedback is:

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Item #2—Current dilemma with OHA BioWatch is that they currently want to use the PSAA standard to qualify their assays for pulling Public Health level action triggers. PSAA (SPADA via AOAC contracts) was meant to provide a test qualification standard for screening assays used by traditional first responders.
Item #3—The NIST issue has some prior (forgotten history) on how the policy path was decided by DHS. There is not actually a hard requirement to use the SPADA type process. There are actually exemptions, which include exigencies associated with preparedness and response, that DHS decided not to take. Joel Ackelsburg (NYC)and I made this clear to them back in the day. The "pay to play" model that they developed has been an acknowledged failure relative to sustainment with the assay developers for the first responder community. I especially know this from my last two years of work on (and report from) the interagency Hand Held Assay WG with Bert Coursey (at DHS from NIST) and Matt Davenport (at DHS and funding SPADA with AOAC contractor).
Richard

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Friday, September 09, 2011 11:40 AM
To: Kellogg, Richard (CDC/OID/NCEZID); [redacted]; Merlin, Toby (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Tara O'Toole

I bumped into Tara while visiting DHS yesterday and we rode up the elevator together. I took the opportunity to put in a good word for Pillai and our work with him and Tara jumped right into the PHAA/BioWatch issue (I rode to her floor for a bit more time to talk!).

Tara asks good questions and wants to do the right things here, but also wants our support, particularly in communicating with Alex Garza and OHA if we think PHAA is the right standard.

1. I shared support for the PHAA model developed over multiple years of deliberation and she asked if it was "too rigorous". I find it hard to believe that when it comes to taking actions involving human life we can be too rigorous, the cost balance does seem to be an issue. In addition to being sure ourselves that this is the right

standard, we might want to consider getting support elsewhere. FDA commented on the process, I believe, but don't recall how that endorsement came out.

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It might be good to follow up with Pillai to be clear what S&T wants/needs from us to keep this methodology in play.

Thanks,

Dan

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Atlanta, GA 30333
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Document 41

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, October 13, 2011 10:11 AM
To: 'Pillai, Segaran'
Subject: RE: Signatures on current PHAA document

Pillai,

Thanks for the clarification. That is very helpful. I have not understood exactly why Biowatch is hung up over PHAA, except that occasionally they want to refer to Gen-3 results as public health actionable (and I have disagreed with them).

Thx,

Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 10:07 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
Please share with Beth, that there were three process to support standards for biodetection out of DHS S&T.

1. Public Safety Actionable Assay which was intended to support the evaluation of Field Screening Assays manufactured of commercial companies for First Responder Use. The conops associated with this effort is directly attributed to saftey related actions such as evacuation of buildings, decon of potentially exposed individuals, expediting the transfer of sample to the LRN for confirmation etc. In addition to the above regardless of whether a sample is positive or negative, the sample is still forwarded to a LRN lab for secondary testing to eliminated False Positives and False Negatives

2. Federal Standards for Assay Performance and Equivalency. This was specifically design to support and fulfill the National Biomonitoring Program and under a MOU signed among Asst Sec. from DoJ, DoD, HHS, DHS and USPS which all had a biomonitoring program at that time. The task was delegated to DHS S&T to implement a process for for establishing Assay performance Equivalence among the programs so the federal partners recognize the credibility to support the initiation public health response in a timely manner. This is the effort Garza is referring to. We actually briefed CDC leadership about a year ago during Lisa Rotz time to Ali, Beth, Dan and others and they already signed off on it just like all the other agencies except of OHA and USPS at the current time. The issues with USPS is being dealt by NSS because they just don't have the money to continue and operate the BDS and they are the process of reevaluating the program (please hold this information close. This is not for sharing at the current time). With regards to OHA, we have forwarded all the versions multiple time over the past several years and they keep ignoring and not truly engaging in the effort although we have tried many time. They have come up with multiple excuses over the years and questions which we had address all of them. So, I don't know what their true concerns are, but for a high profile program like BioWatch, it will be in their best interest to put their assays and system through a robust process to ensure they function and operate at an optimal level to support the Nation with an early warning of a biological attack. Several months ago Mike Farrell from the BRRAT lab evaluated the Assay Chemistry being used by the NG Gen 3 system at the request of OHA BioWatch program. His finding were similar to our findings when we did the evaluation of Gen 2.5 the Bioplex assays. That is the assay chemistry is fundamentally flawed and have to be addressed immediately and had shared this with OHA. As per Mike, they ignored is and upon Mike revisiting this issue, they shared with him that they will fix it after procurement which is highly troubling (please check with Mike for specifics). I don't know if OHA BioWatch is worried that if they were to put the assays through the FSAPE process they might failed and is trying to bypass it. They have insisted to us that the PSAA process is a better process and as such want to put their systems through that process which was intended for Public Safety Actions. My thoughts on this is that they can go through the process and if they get a positive signal, they can retrieve the sample from the detectors and take to the closest LRN Lab for confirmation, however if they were to miss a detection, there is no mechanism to capture it (referring to false negative result) simply because the negative samples will not be retrieved and taken to a LRN Lab for secondary testing.

3. Public Health Actionable Assays. This is specifically to support the assay development, evaluation, validation and certification of the assays deployed and employed through the CDC LRN. This has nothing to do with OHA or BioWatch.

This is strictly related to the LRN assays to support National BioPrepardness and Defense and Public Health Surveillance mission. These assays are intended to be highly robust for use in a LRN laboratory to evaluate environmental samples that comes to the lab, support epi investigation associated with a bioterrorism event as well as clinical sample to support medical and clinical intervention. We worked with many folks form CDC all the way from LRN TRC director, LRN Manager, Environmental Microbiology Director, SME Lab Directors, Branch Chiefs and Division Directors for the input and contribution to the PHAA plan simply because we wanted to ensure that the assays deployed and employed through the CDC LRN are highly robust to support the mission.

Hope this helps and I am on travel to the West Coast and will return back to the office next week. If you would like to chat, please let me know and I can give you a call at you convenience. Take care.

Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thu Oct 13 08:53:21 2011
Subject: RE: Signatures on current PHAA document

Pillai,

I'm going to get the specifics from Beth again, because I want to be sure I get them right, and I will send them along later. I think they primarily have to do with the impression that the Biowatch program and Gen-3 will have to meet PHAA standards and be approved by PHAAC as a condition of deployment. But, let me see exactly what Beth says.
Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 8:31 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
Can you please share with me the concerns raised by Alex to Beth pertaining to the PHAA? Thanks and appreciate your help and assistance on this. Take care.
Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Wed Oct 12 11:42:41 2011
Subject: Signatures on current PHAA document

Pillai,

I met with Beth Bell and other members of our Center leadership yesterday, and we discussed the requested signatures on the PHAA document. Beth tells me that she recently met with Alex Garza from DHS-OHA where he explicitly raised his concerns about PHAA. We seem to be at a juncture where DHS-S&T and DHS-OHA need to resolve their internal disagreements over PHAA and present us with a PHAA document for CDC signature that has cleared stakeholders at DHS. Personally I believe there is a critical need for standards and the differences between DHS-OHA and DHS S&T are resolvable.

I am willing to discuss and help in any way you like.

Thanks,

Toby

Document 42

[redacted]

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Wednesday, October 19, 2011 7:48 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Toby, Agree. The amount of animosity between the 4th and 6th floor is pretty evident from time to time. More than happy to chat whenever your schedule permits or during our time in ATL.

Travel safe,
Jim

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, October 19, 2011 5:23 AM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim, We at CDC often seem to be caught in the middle of the DHS-OHA DHS S&T dispute. I actually think a lot of this could be resolved, at least in regard to the substantive issues, if the parties put their minds and hearts to it. We should certainly talk about this.
Best,
Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 9:23 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Hi Toby,

Just in and seeing your message...I'm still waiting on my DHS blackberry.

Alex and I chatted a bit about these issues. The OHA-S&T looks to not be getting better.

Feel free to ring me up if you'd like, I'll be up for a bit.

Thanks for the potential dates Toby..I'll forward down to the folks in ATL doing the scheduling.

Jim

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 5:49 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim,
Here is the list of things that I would like us to discuss:

1) The interface between Biowatch and public health

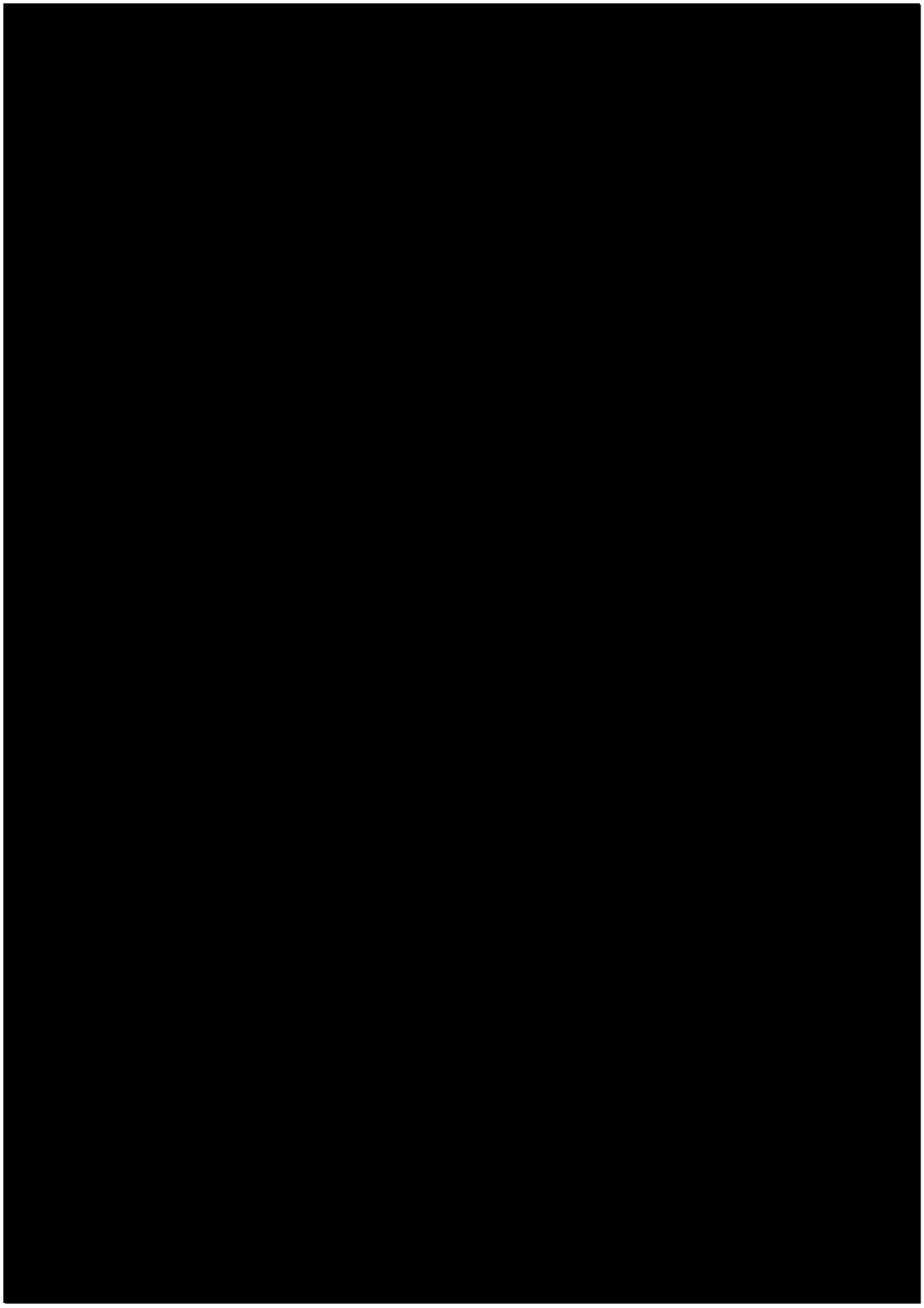
2) Our concerns about the Gen-3 program
3) The strained relationship between DHS-OHA and DHS-S&T on standards for testing for biothreat agents.

I'm going to send you a copy of my calendar for the dates when you'll be in Atlanta. Let me know what works best for you for us to meet. I am tentatively scheduled to travel to DC on November 2 for an anthrax meeting, but that may change.

I very much enjoy working with Mike Walter and Ulana, and I know Sally Philips and she's great. I think you've got a very good job.

Best,

Toby



[redacted]

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 5:15 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Should have said.....No worries. I'd say enjoy but....

Big Fingers on an IPad

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 4:52 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim, This meeting here just keeps going on and on, and I can't break away. I am going to send you an email a little later that outlines some things we can talk about later.
Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 1:06 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Toby,

Both of those times are in my prime sleep band but for you I'll make an exception...ha,ha

I'm good with either and should be able to accommodate....your call , literally and figuratively.

Looking forward to chatting and working with you as well my friend.

Thanks,
Jim

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 12:51 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim,

It's going to be great having you at DHS-OHA and to get to work with you again. As you have heard from Ulana, I am in regular touch with her and Mike about the Biowatch program and other related laboratory testing activities. I am traveling this week, but I would like to talk with you for maybe 30 minutes before you head over to Biowatch. This afternoon after 5 or tomorrow morning before 9 would make it easiest to work around my anthrax meetings here.

Best,

Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 10:39 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: BioWatch and such

Hi Toby,

Hope all is well on your side of the Mason-Dixon Line and the new job is working out.

I've chatted with Ulana a bit and will be heading over to BioWatch on Friday to spend some time so I wanted to check in to see if there were any issues you'd like me to look in on while I am there. I realize that you and your folks are pretty hardwired there already but thought I would ask.

Planning on being down your way on 31OCT-2NOV and hope to get an audience with you and Steve to see how I can facilitate for you up this way.

Look forward to catching up in a slower paced (at least for me) environment than the EOC.

James Hayslett, PharmD, MPH
DHS/OHA Liaison Officer
DHHS/CDC/OPHPR/OD
Washington, DC

[redacted]

Document 43

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:59 PM
To: Hayslett, James (CDC/OPHPR/OD)
Cc: [redacted] (CDC/OID/NCEZID)
Subject: Follow-up from Toby Merlin to NYC DOH

Jim,

This outlines some of the steps on improved guidance that we/CDC need to work on with Biowatch.

Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:51 PM
To: 'Colin Stimmler'; Weisfuse, Issac (CDC health.nyc.gov); Beth Maldin
Cc: [redacted]
Subject: RE: Draft DHS OT&E Guidance

Colin, Beth, and Issac,

Thanks for asking us to the exercise yesterday. It was very helpful for us both to see the dynamics of the situation you all are in with regards to a single BAR. Thanks also for the OT&E document.

Issac, I would like an electronic copy of your "Asks" one pager, if you could send it to me.

On my call today with Mike Walter and Ulana Bodnar, we did discuss several of the issues that were raised in our meeting at DOH yesterday. And, here's the follow-up:

1) Biowatch Program and CDC agree on the need to develop federal guidance for how jurisdictions should handle a single BAR. Mike Walter is going to take the lead with CIDRAP in setting up a focus group with Biowatch, CDC, NYC and a few other large cities to work on this.
2) Biowatch Program and CDC agree on the need to develop federal guidance or plans for management of environmental sampling after detection of an event. Mike Walter is going to take the lead on this.

I will send you follow up on the others items discussed later.
PS: We got a taxi pretty quickly on Broadway, got to the hotel and then to the airport with plenty of time to spare.

Thanks,

Toby

From: Colin Stimmler [mailto:cstimmle@health.nyc.gov]
Sent: Thursday, November 17, 2011 11:28 AM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: Beth Maldin; Weisfuse, Issac (CDC health.nyc.gov)
Subject: Draft DHS OT&E Guidance

Hi Toby [redacted],
Thanks again for meeting with us yesterday. As requested attached is the draft DHS OT&E Guidance. Let me know if you need anything else.

Colin

Colin Stimmler

Document 44

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:57 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: FW: Letter we/DPEI are sending to DHS-OHA about our concerns on Gen-3 ORD

Jim,

I will send you emails to keep you in the loop on major activities. As I discussed with you when you were here, we have sent this letter below to Mike Walter and Bob Rahnhofer. I spoke with Mike today, and it seems that it was acceptable. Beth has let Ali know.

I understand that the ORD is currently derailed while the sensitivity issue is being addressed. It's interesting. I don't think anyone actually knows the sensitivity of the current PSU system for detecting bacteria or viruses in actual aerosols.

Best,

Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, November 15, 2011 11:10 AM
To: Bell, Beth (CDC/OID/NCEZID)
Subject: Letter we/DPEI are sending to DHS-OHA about our concerns on Gen-3 ORD

Beth,

Below and attached is the letter that Mike Farrell (who serves as our technical representative to the Gen-3 ORD) and I drafted this past weekend, and which we are sending to the Gen-3 team at DHS-OHA. It identifies our major areas of concerns about the device and technology. One thing that it doesn't mention is that DHS-OHA is proceeding with operational testing and evaluation at 4 or 5 select cities, before they have gotten a device that actually works.

Thanks,

Toby

November 14, 2011

Mr. Robert Ranhofer
Acquisition Director, Gen-3 Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dr. Michael Walter
Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dear Bob and Mike:

This letter is in response to your emails dated Friday, October 28 and Wednesday, November 9 requesting CDC concurrence on the updated Operational Requirements Document (ORD) version 2.1 dated September 12, 2011 for the Biowatch Gen-3 Autonomous Detection System.

From our discussion at the annual BioWatch conference in Tampa, FL, your emails, and the comment resolution matrix, we understand that you feel that our concerns about the Gen-3 system can and will be addressed without modifying ORD v2.1. With your assurances that our concerns will be addressed as the procurement process moves forward and before operational deployment, we are willing to provide our concurrence to ORD v2.1. We are requesting that you acknowledge the concerns that we feel need to be addressed for an acceptable operational system:

1. The system sensitivity specified in [redacted] is not sufficient to detect concentrations of organisms in aerosols that can cause disease in humans. From your email dated October 28, it appears that a change in sensitivity might be forthcoming,
2. The key performance parameter for the threshold only specifies Francisella tularensis and does specifically exclude the F. tularensis subspecies or near neighbors known to cause frequent BARS in the current Biowatch system.
3. There are concerns specific to the current NG-ADS system, which become material should that system proceed into the next phase of the procurement:
    a. Thirteen of the pathogen detection assays being used in the current NG-ADS system are LRN assays of which several of them, in particular YPMT2, YPMT9, YPMT12, YPMT16, FT1, FT2, and FT3 are known by both our programs to cross react with non-target organisms endemic in some regions of the country. These supposed near-neighbor organism are collected on the BioWatch air filters and have frequently been the cause of false positive laboratory results. In our opinion, these assays are not suitable for the purposes stated for the Gen-3 system.
    b. Nine of the pathogen detection assays being used in the current NG-ADS system, in particular BA2, MP2, MP3, YPMT2, YPMT9, YPMT16, VRL1, VRL2, and VRL4 seem to have detection probe designs that are not complementary to the captured biotinylated PCR product strand, but rather complementary to the PCR product strand that is not captured. Despite the fact that this flawed chemistry has demonstrated that it can detect pathogens from near neighbors, it is not clear exactly how this happens. Either the formation of a tripartite structure between the probe and both the biotinylated and non-biotinylated PCR product strands occurs, or an overabundance of the biotinylated forward primer that exists after the PCR reaction may be responsible. Regardless, this flawed chemistry/design is extremely worrisome especially in the context of a constantly changing and complex sample matrix such as an air collection sample.

We understand that the procurement process is complicated, and we hope this provides an adequate mechanism of both acknowledging our concerns that need to be addressed and providing concurrence to the ORD.

We would be happy to discuss further, if you like.

Sincerely,

ORD 2.1 contigent concurrence ...

November 14, 2011

Mr. Robert Ranhofer
Acquisition Director, Gen-3 Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dr. Michael Walter
Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dear Bob and Mike:

This letter is in response to your emails dated Friday, October 28 and Wednesday, November 9 requesting CDC concurrence on the updated Operational Requirements Document (ORD) version 2.1 dated September 12, 2011 for the Biowatch Gen-3 Autonomous Detection System.

From our discussion at the annual BioWatch conference in Tampa, FL, your emails, and the comment resolution matrix, we understand that you feel that our concerns about the Gen-3 system can and will be addressed without modifying ORD v2.1. With your assurances that our concerns will be addressed as the procurement process moves forward and before operational deployment, we are willing to provide our concurrence to ORD v2.1. We are requesting that you acknowledge the concerns that we feel need to be addressed for an acceptable operational system:

1. The system sensitivity specified in [redacted] is not sufficient to detect concentrations of organisms in aerosols that can cause disease in humans. From your email dated October 28, it appears that a change in sensitivity might be forthcoming,
2. The key performance parameter for the threshold only specifies Francisella tularensis and does specifically exclude the F. tularensis subspecies or near neighbors known to cause frequent BARS in the current Biowatch system.
3. There are concerns specific to the current NG-ADS system, which become material should that system proceed into the next phase of the procurement:
    a. Thirteen of the pathogen detection assays being used in the current NG-ADS system are LRN assays of which several of them, in particular YPMT2, YPMT9, YPMT12, YPMT16, FT1, FT2, and FT3 are known by both our programs to cross react with non-target organisms endemic in some regions of the country. These supposed near-neighbor organism are collected on the BioWatch air filters and have frequently been the cause of false positive laboratory results. In our opinion, these assays are not suitable for the purposes stated for the Gen-3 system.
    b. Nine of the pathogen detection assays being used in the current NG-ADS system, in particular BA2, MP2, MP3, YPMT2, YPMT9, YPMT16, VRL1, VRL2, and VRL4 seem to have detection probe designs that are not complementary to the captured biotinylated PCR product strand, but rather complementary to the PCR product strand that is not captured. Despite the fact that this flawed chemistry has demonstrated that it can detect pathogens from near neighbors, it is not clear exactly how this happens. Either

the formation of a tripartite structure between the probe and both the biotinylated and non-biotinylated PCR product strands occurs, or an overabundance of the biotinylated forward primer that exists after the PCR reaction may be responsible. Regardless, this flawed chemistry/design is extremely worrisome especially in the context of a constantly changing and complex sample matrix such as an air collection sample.

We understand that the procurement process is complicated, and we hope this provides an adequate mechanism of both acknowledging our concerns that need to be addressed and providing concurrence to the ORD.

We would be happy to discuss further, if you like.

Sincerely,

Document 45

[redacted]

From: Beth Maldin <bmaldin@health.nyc.gov>
Sent: Thursday, November 17, 2011 3:35 PM
To: Merlin, Toby (CDC/OID/NCEZID); Colin Stimmler; Weisfuse, Issac (CDC health.nyc.gov)
Cc: [redacted]
Subject: RE: Draft DHS OT&E Guidance
Attachments: BioWatch Asks of CDC 20111115.docx

Thanks again for coming and glad to hear your trip home was uneventful! We look forward to hearing more about 1 and 2 below as well as anticipated timelines. We will also be interested in sharing what we have developed so far to provide a starting point and get your feedback.
Thanks again!
Beth

From: Merlin, Toby (CDC/OID/NCEZID) [mailto:tfm5@cdc.gov]
Sent: Thursday, November 17, 2011 2:51 PM
To: Colin Stimmler; Isaac Weisfuse; Beth Maldin
Cc: [redacted]
Subject: RE: Draft DHS OT&E Guidance

Colin, Beth, and Issac,

Thanks for asking us to the exercise yesterday. It was very helpful for us both to see the dynamics of the situation you all are in with regards to a single BAR. Thanks also for the OT&E document.

Issac, I would like an electronic copy of your "Asks" one pager, if you could send it to me.

On my call today with Mike Walter and Ulana Bodnar, we did discuss several of the issues that were raised in our meeting at DOH yesterday. And, here's the follow-up:

1) Biowatch Program and CDC agree on the need to develop federal guidance for how jurisdictions should handle a single BAR. Mike Walter is going to take the lead with CIDRAP in setting up a focus group with Biowatch, CDC, NYC and a few other large cities to work on this.
2) Biowatch Program and CDC agree on the need to develop federal guidance or plans for management of environmental sampling after detection of an event. Mike Walter is going to take the lead on this.

I will send you follow up on the others items discussed later.
PS: We got a taxi pretty quickly on Broadway, got to the hotel and then to the airport with plenty of time to spare.

Thanks,
Toby

From: Colin Stimmler [mailto:cstimmle@health.nyc.gov]
Sent: Thursday, November 17, 2011 11:28 AM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: Beth Maldin; Weisfuse, Issac (CDC health.nyc.gov)
Subject: Draft DHS OT&E Guidance

Hi Toby & Steve,
Thanks again for meeting with us yesterday. As requested attached is the draft DHS OT&E Guidance. Let me know if you need anything else.

Colin

Colin Stimmler
Director - BioWatch Planning & Special Projects
Office of Emergency Preparedness and Response
NYC Dept of Health & Mental Hygiene
2 Gotham, Queens (6-94)
[redacted]

Asks for the Federal Government: Before, During and After a BioWatch Actionable Result (BAR)

1. Federal public health planning and response
    a. There is no detailed consensus on what a federal response to a BAR would look like (roles, responsibilities)
    b. Not clear who at the Federal level has responsibility for developing and coordinating potential response to a BAR
    c. Federal indemnification for the City of New York in the event of a false reactive identification of an organism relating to a BAR.

2. Federal guidelines: remediation methods and re-occupancy criteria
    a. Remediation: No standard methods for remediation so every jurisdiction may approach this differently
    b. Re-occupancy: Lack of realistic standards for remediation and re-occupancy (Following large-scale contamination the objective to remediate and re-occupy contaminated buildings within weeks to months, not years). For example, estimates range from 50 – 300+ years to complete NYC cleanup after wide area anthrax release using the 2001 remediate and re-occupancy standards (federal standards: zero acceptable risk)
    c. Characterizing the scope and scale of the incident: Characterizing the scale and scope of incident- including testing of subway train ventilation filters to rule-in likelihood of subway exposures
    d. Equipment: Evaluate use of handheld or portable field instruments for use in characterization and in remediation post-BAR (rather than sending samples to a lab), critical because Public Health Lab will not be able to analyze the number of samples that we imagine will be collected for full site characterization and remediation after a bio contaminating event in an indoor facility
    e. Decontamination: Human decontamination & Guidance on disposal or washing of clothing
    f. Surrounding area: Recommendations for buildings in the area of an outdoor and indoor facility BAR (e.g., evacuate, close windows, turn off HVAC, etc.) and setting perimeter.

3. Modeling Tools
    a. Expand current BioWatch Indoor Reach Back Center (BIRC) modeling from current indoor locations to adjacent facilities, subways, and outdoor areas to understand impact of outdoor venting
    b. Need further modeling on the risk in subways and re-suspension after continued operation.

4. Laboratory support
    a. Surge capacity for laboratory materials- reagents and environmental sampling materials
    b. Coordination of sending out samples for surge testing within LRN
    c. Guidance on post-BAR surge testing (e.g., direct verification without screening; efficacy of increasing the tempo of PSU collections and testing)
    d. Continued engagement with DHS on Gen 3 program.

5. Surge capacity
    a. Epidemiology staff surge capacity
    b. Medical Surge capacity
    c. Environmental Sampling surge capacity – sampling personnel to assist with incident characterization and mitigation including return to service of critical infrastructure and verification of remediation.

6. Timing and Amount of assets for Mass Prophylaxis
    a. Timing, status, and availability of Anthrax vaccine and other therapeutics, including anthrax immune globulin or antitoxins, and materials needed for mass casualty response.

Document 46

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Sunday, May 06, 2012 11:11 AM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Follow-up on NYC Biowatch concerns

Beth,

I got a chance to speak briefly with Jay Varma about the NYC Biowatch concerns. I think the bottom line is that NYC public health feels that public health is struggling to be heard in a program that is dominated by DHS and law enforcement but which has huge implications for public health departments. This seems to be most acute in NYC, where the police and fire department dominate the policy making.

As you know we have been aware of these concerns and have been taking steps to improve the situation. I thought it would be useful for me to enumerate them explicitly, so that you are aware of what we are doing the next time this comes up:

1) I have been taking a much more active role in engagement with Biowatch than previous Division leadership.
2) I have appointed new Division liaisons to the Biowatch program, which should provide us a much more effective voice.
3) I am personally attending the Biowatch national meetings where major policy decisions are discussed.
4) We are reviewing and commenting on the new Biowatch indoor and outdoor guidance documents.

The limitation of this, of course, is that DHS/Biowatch is still in the lead on these policies, and it will take some time to influence the direction. Steve Papagiotas and I will be seeing members of the NYC Biowatch Advisory Committee at the Biowatch indoor guidance meeting this week, and I will review with Colin Stimmler from NYCDOMMH the steps we are taking.

Toby

Document 47

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 16, 2012 12:08 PM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [redacted], Holmes, Harvey T. (CDC/OID/NCEZID); [redacted]
Subject: RE: Question to follow-up Biowatch Indoor Working Group

Let's walk/talk through this with you, Geoff, Steve and Mike by phone or in person, so that I am sure that I understand.
Thx,
Toby

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Wednesday, May 16, 2012 12:02 PM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: [redacted], Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: RE: Question to follow-up Biowatch Indoor Working Group

More information to answer question : Have the number of Ft screens positives and BARS decreased since the implementation of CRP reagents and the QA program?

From August 2010 to August 2011 there were approximately 635 out of 1828 (35%) screen reactives for Ft with a CT value >=40. Of the 23 BARs reported in the email below for the same time period, 8 had all 3 signatures with CT value >=40 . Four of these were in Houston

From August 2011- May2012 there were potentially 91 screen reactives with CT value >=40 , most of which were called negative. If these were all called reactive there would have been about 20% of reactives with CT over 40. This includes reactives on the CRP panel.

The number of reactives decreased from 1828 to 370. The number of BARS for Ft has decreased as well. I believe the change in CT value and the QA program cotributed to this decrease.

Jasmine
LRN Program Office

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Thursday, May 10, 2012 10:42 AM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: [redacted]
Subject: RE: Question to follow-up Biowatch Indoor Working Group

I have to look at data more closely and of course there are a number of other factors that contribute to whether or not an FT BAR is declared. Here is initial assessment of number of FT BARs for comparable time periods. In August 2011 the program implemented the new CT cut off of 40 cycles.

August 2010-May 2011: 23
August 2011-May 2012: 4

Jasmine

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 09, 2012 12:32 PM
To: [redacted] Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [redacted]
Subject: RE: Question to follow-up Biowatch Inddor Working Group

It would be good to know how much of the reduction has been due to reduction of Ct threshold versus use of CPR reagents versus the QA program.
Toby

From: [redacted]
Sent: Wednesday, May 09, 2012 11:49 AM
To: Merlin, Toby (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Re: Question to follow-up Biowatch Inddor Working Group

Hello,

In the absence of actual numbers, I would say yes but due mainly to our decision to reduce the cutoff for Ct values from 45 to 40.

Jas may have actual numbers to support the reduction in reactives.

[redacted]
Sent from Geoff Jackson's Blackberry device

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 09, 2012 11:43 AM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Question to follow-up Biowatch Inddor Working Group

Have the number of Ft screens positives and BARS decreased since the implementation of CRP reagents and the QA program?

Thx,

Toby

Document 48

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 23, 2012 9:53 AM
To: Bell, Beth (CDC/OID/NCEZID); [redacted]
Subject: Thoughts for 11:30 call about Beth's upcoming meeting with Tara O'Toole

This is going to sound a lot like a justification for a liason in Tara O'Toole's office.

There is a lot that happens at DHS S&T that has profound impact on public health downstream, and we could better understand and mitigate these decisions if we had some sort of seat at the table. Here are some examples:

1) The material threat assessments (MTA) which DHS is required to perform by statute. These drive the downstream decisions about medical countermeasure acquisition, diagnostic test development, Biowatch testing, and preparedness plans. But the MTAs seems to be developed without input from people who really understand the agents, diseases, or practical implications of these decisions.
2) S+T R+D agenda. This also has profound impacts on public health, and we would benefit if our voice were heard.

Toby

Document 49

[redacted]

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 7:09 PM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [redacted]
Subject: RE: biowatch story

Categories: Red Category

Ali, glad to discuss further however you would like. I would say that the operational and technical problems may not be surmountable, ie I am not sure there is a technology good enough to work the way DHS has envisioned BW Gen 3 to function. Let us know if you'd like to meet or what. Toby Merlin has thought most comprehensively about this topic.

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Wednesday, June 20, 2012 12:02 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [redacted]
Subject: Re: biowatch story

Beth:

This is very helpful.
So tactically, this specific device appears to be premature for deployment for various reasons.

I will want to follow up with you to solicit your strategic assessment of the Biowatch program given your Center's and personal experience all these years? Are the technical and operational issues in BW Gen 3 requirements surmontable or a proxy for our way of saying BW is a bad idea? Could BW be a good idea with better technology and some changes in approach such as limited to maybe anthrax? We should assure we have a single Agency position as we interact with DHS.

Thanks again,

Ali

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 06:05 AM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); [redacted] Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Ali, Toby says that the Gen 3 program is being reviewed by Judge Mary Hill, who as you know is a trusted confidant of Janet Napolitano; they have known each other since law school. It was initially prompted by the GAO or OIG study. Toby says that some folks at DHS have been encouraging Mary Hill to talk to folks at CDC to get their take on Biowatch and Gen3, which may be the reason for the call from Tara O'Toole.

As for our opinions about Gen 3, we have a number of concerns as outlined in a general way by Toby below. We sent a detailed letter with our technical concerns mostly around #1 to DHS at the time they were

last reviewing their contract. Happy to send that if you'd like, or expand on the below. We have communicated these concerns to the biowatch program.

1) Currently CDC and others (DHS S&T) have identified serious problems with the specificity and sensitivity in the Gen3 system under development by Northrop Grumman. On a day to day operational basis, we are most immediately concerned about the risk for false positives which could be a regular occurrence.

2) The Gen3 system generates positive results which would require investigation and confirmation before action could be taken on these results. There is currently no concept of operations for how this investigation and confirmation would take place.

3) The Gen 3 system is being deployed to Biowatch sites before the device has been shown to work effectively.

Beth

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:37 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); [redacted] Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Beth:

As discussed earlier today, your professional judgment of the BioWatch program including the new Gen-3 expansion would be very helpful and appreciated for my upcoming conversation with Tara. Recognizing that DHS money is not going to be diverted to CDC, is there anything we see worthwhile in that program? Although the cost is an abomination and a positive reading will still require somebody to go get the canister and cut into the purported timeliness.

The underlying premise was originally considered sound from a national security perspective – no different from NORAD. A network of monitors in select cities to detect aerosol releases of high hazard agents to give public health a head start to prophylaxis.

Thanks,

Ali

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:01 PM
To: [redacted] Khan, Ali S. (CDC/OPHPR/OD); [redacted] Bell, Beth (CDC/OID/NCEZID)
Subject: RE: biowatch story

Catch the caption on the photo! Funny how bad information can come from upstanding news organizations. VaxGen was a high profile BARDA "failure" and there is no VaxGen anthrax vaccine in the SNS.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer

Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333
[redacted]

From: [redacted]
Sent: Tuesday, June 19, 2012 3:51 PM
To: Khan, Ali S. (CDC/OPHPR/OD); Sosin, Dan (CDC/OPHPR/OD); [redacted]; Bell, Beth (CDC/OID/NCEZID)
Subject: biowatch story

Washington Post

http://www.washingtonpost.com/business/economy/anthrax-alert-system-at-risk-as-cost-estimate-hits-57-billion/2012/06/18/gJQAZQwTkV_story.html

[redacted]

RADM, USPHS

Director, Influenza Coordination Unit

Document 50

[redacted]

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Thursday, June 21, 2012 1:43 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [redacted]
Subject: RE: biowatch story

Thank you for the offer Beth, that would be very helpful. I'll ask Barbara to set something up.
And please also keep in confidence that Tara is asking about BW. There are some very severe politics in DHS right now.
Best,
Ali

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 7:09 PM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [redacted]
Subject: RE: biowatch story

Ali, glad to discuss further however you would like. I would say that the operational and technical problems may not be surmountable, ie I am not sure there is a technology good enough to work the way DHS has envisioned BW Gen 3 to function. Let us know if you'd like to meet or what. Toby Merlin has thought most comprehensively about this topic.

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Wednesday, June 20, 2012 12:02 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [redacted]
Subject: Re: biowatch story

Beth:

This is very helpful.
So tactically, this specific device appears to be premature for deployment for various reasons.

I will want to follow up with you to solicit your strategic assessment of the Biowatch program given your Center's and personal experience all these years? Are the technical and operational issues in BW Gen 3 requirements surmontable or a proxy for our way of saying BW is a bad idea? Could BW be a good idea with better technology and some changes in approach such as limited to maybe anthrax? We should assure we have a single Agency position as we interact with DHS.

Thanks again,

Ali

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 06:05 AM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); [redacted] Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Ali, Toby says that the Gen 3 program is being reviewed by Judge Mary Hill, who as you know is a trusted confidant of Janet Napolitano; they have known each other since law school. It was initially prompted by the GAO or OIG study. Toby says that some folks at DHS have been encouraging Mary Hill to talk to folks at CDC to get their take on Biowatch and Gen3, which may be the reason for the call from Tara O'Toole.

As for our opinions about Gen 3, we have a number of concerns as outlined in a general way by Toby below. We sent a detailed letter with our technical concerns mostly around #1 to DHS at the time they were last reviewing their contract. Happy to send that if you'd like, or expand on the below. We have communicated these concerns to the biowatch program.

1) Currently CDC and others (DHS S&T) have identified serious problems with the specificity and sensitivity in the Gen3 system under development by Northrop Grumman. On a day to day operational basis, we are most immediately concerned about the risk for false positives which could be a regular occurrence.

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3) The Gen 3 system is being deployed to Biowatch sites before the device has been shown to work effectively.

Beth

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:37 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); [redacted]; Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Beth:

As discussed earlier today, your professional judgment of the BioWatch program including the new Gen-3 expansion would be very helpful and appreciated for my upcoming conversation with Tara. Recognizing that DHS money is not going to be diverted to CDC, is there anything we see worthwhile in that program? Although the cost is an abomination and a positive reading will still require somebody to go get the canister and cut into the purported timeliness.

The underlying premise was originally considered sound from a national security perspective – no different from NORAD. A network of monitors in select cities to detect aerosol releases of high hazard agents to give public health a head start to prophylaxis.

Thanks,

Ali

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:01 PM
To: [redacted] Khan, Ali S. (CDC/OPHPR/OD); [redacted]; Bell, Beth

(CDC/OID/NCEZID)
Subject: RE: biowatch story

Catch the caption on the photo! Funny how bad information can come from upstanding news organizations. VaxGen was a high profile BARDA "failure" and there is no VaxGen anthrax vaccine in the SNS.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333
[redacted]

From: [redacted]
Sent: Tuesday, June 19, 2012 3:51 PM
To: Khan, Ali S. (CDC/OPHPR/OD); Sosin, Dan (CDC/OPHPR/OD); [redacted]; Bell, Beth (CDC/OID/NCEZID)
Subject: biowatch story

Washington Post

http://www.washingtonpost.com/business/economy/anthrax-alert-system-at-risk-as-cost-estimate-hits-57-billion/2012/06/18/gJQAZQwTkV_story.html

[redacted]

RADM, USPHS

Director, Influenza Coordination Unit

Document 51

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, June 29, 2012 2:50 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: Life, Liberty and the Pursuit of Assays

Jim,

I really don't know. Mike has not identified anything to me. A few things come to mind, but nothing new:

1) I was vocal at the Indoor Guidance meeting.
2) We have been trying to get the Biowatch program to better define what a BAR is.
3) We did provide extensive requested comments on the requested Biowatch Outdoor Guidance.

Mike and I used to have monthly calls before Ulana left, and now we don't. Do you think I should reach out to Mike and just ask him how things are going?

Thanks,

Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Friday, June 29, 2012 1:45 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Life, Liberty and the Pursuit of Assays

Hi Toby,

Hope all is well down your way and it is cooler than here.

Alex and I were chatting earlier and he mentioned that Mike Walter came to him regarding some issues with CDC and PHAAs that were causing Mike some consternation.

Alex had asked that I touch base to get some background/insight that would be useful for him to understand the CDC position.

Apologies that this is a bit cryptic but Alex didn't have all the details when we talked.

Thanks in advance,
Jim

Document 52

[redacted]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:53 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Stephen,
The 37/37 would reflect specificity, not sensitivity. He makes no claim regarding sensitivity.
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:51 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Hi Toby,

The way I would interpret his statement is:
7 million tests without a false positive = 100% specificity. 37/37 positives were true positives (i.e., "naturally occurring pathogens were detected in environmental samples) = 100% sensitivity. Garza is claiming that all positives were pathogens that are known to occur naturally in the environment.

Thanks,
Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:07 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Stephen,
Thanks for forwarding this. I don't see that Garza claims 100% sensitivity and specificity for Biowatch here. I will work on the text you forwarded.
Thanks!
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 9:37 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Garza's Statement

THURSDA[illegible]

The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack
-Posted by Dr. Alexander Garza,
Assistant Secretary for Health Affairs and Chief Medical Officer for DHS

We all know the importance of early detection in the treatment of diseases and medical emergencies. Routine screenings and monitoring as well as rapid response save thousands of lives every year. The same principles

apply when mitigating the effects of biological threats, which is why DHS works with state and local officials through the BioWatch program to monitor for traces of dangerous pathogens in public places where large groups of people gather to ensure that we respond quickly when a potential threat is identified.

There has been some confusion reported in the news lately about how the BioWatch program works and what it is intended to do. First announced in 2003, BioWatch is the nation's first early detection and warning capability for biological attacks. DHS partners with public health laboratories, which are members of the Centers for Disease Control and Prevention's (CDC) Laboratory Response Network, to conduct rapid analysis and provide information and expertise to governors and local emergency officials when a pathogen is detected in order to determine whether it indicates a potential biological attack.

Recent media reports have incorrectly claimed that BioWatch is prone to "false positives" or "false alarms" that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result.

Out of these more than 7 million tests, BioWatch has reported 37 instances in which naturally-occurring biological pathogens were detected from environmental sources. Many of the pathogens the BioWatch system is designed to detect occur naturally in the environment, such as the bacteria that causes anthrax, which has been used as a weapon, but is also found in nature. For example, near the nation's Southwest border there have been a number of instances where a bacterium that is endemic in the environment has been identified. Thankfully, none of the instances were actual attacks. The detection of commonly occurring environmental agents is not a "false positive."

Much like a home smoke detector goes off for both burnt toast and a major fire, the smoke detector is meant to notify you of a potential fire before it's too late. BioWatch works very much the same way. If BioWatch detects a potential threat, state and local officials as well as first responders have the ability to investigate the incident to the fullest and determine if there is a credible threat to the public.

These tools alone cannot and do not declare that a biological attack has occurred. Experts must interpret the data and quickly make tough, logical decisions about the reality of the threat. BioWatch is designed to provide the nation with the greatest lead time possible to respond to the potential release of a biological agent. The faster we detect an event, the more lives we can save by responding and delivering medical countermeasures. Looking forward, the scientists who operate the system will continue their work to improve BioWatch to keep the nation safe from any potential biological threats.

Document 53

[redacted]

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:52 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Toby,

I agree with your comment whole heartedly. Unfortunately, the hype is different than reality.

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:44 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Stephen,
Candidly, I do not believe that a high consequence action can be initiated based only a BAR, even if the test methodology conforms to PHAA. There are many other potential sources of error than just cross reactivities.
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:34 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Hi Toby,

With the current BioWatch system, filters are collected and analyzed in a laboratory. Thus, there is a delay between when the release occurred and when it was detected through laboratory analysis. Confirmation may occur in the same laboratory facility. In Gen3, they envision that the release would be detected by the autonomous collection/analysis unit and the results sent to a central site where some action would be initiated. I think there is more time for a thoughtful consideration of the data with the current system than what they envision (or hyped) with Gen3. I agree that there is little "bang for the buck" with Gen3 and it is likely to be a casualty of the Country's current fiscal situation.

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:19 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Stephen,

I am not sure there is much of a long term future for Gen3 in the current budgetary environment. That said, Biowatch has already deployed into select indoor environments, where it is problematic to send teams in for phase 1 sampling without evacuating the building.
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:54 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Hi Toby,

I think your changes are great and to the point. One thought though. I heard that BioWatch is considering deploying Gen3 in indoor environments (They may have decided not to but I don't know for sure). Their mantra has been "detect to treat" in order to reduce morbidity and mortality in the event of a release. Thus, it becomes even more important to have high confidence assay results if public buildings are to be evacuated in the event of a BAR, and prior to confirmation.

Thanks for your input,

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:40 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

<< File: TM revisions to SM summary of 07222012.docx >>

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:32 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here's my version of the November 22 meeting for your review.

Hi Toby,

There was no attachment.

Thanks,
Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 5:04 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: Stephen, Here's my version of the November 22 meeting for your review.

Stephen,

This is my version. Of course, only you can say what you said and what you intended.

Toby

Document 54

[redacted]

From: Weber, Angela (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 1:21 PM
To: Merlin, Toby (CDC/OID/NCEZID); Morse, Stephen A. (CDC/OID/NCEZID)
Cc: [redacted] Weber, Angela (CDC/OID/NCEZID)
Subject: Congressional Letter & Mention of "Trace" Detection

Stephen and Toby,

I realize that much attention has been placed on the issues related to Ft. However, I would like to also bring up issues related to how DHS OHA has referred to BioWatch's ability to detect "traces of dangerous pathogen" (refer to question #3 on the Congressional request to CDC).

Since we are being asked about this, I think it's critical that we provide clarification as to why this is misleading. In the course of working on BioWatch, I have heard OHA repeatedly sell this capability as a way to tout how sensitive the assays are at detecting low concentrations of organisms. This is flawed as there is supporting data showing that the collection system is not capable of detecting trace concentrations of organisms (the collector itself is known to leak around the filter). This is an important point to make from the public health standpoint as the system (regardless of whether you are addressing the current system or Gen 3) is not capable of detecting the lower concentrations associated with infectious doses. This is true of all the agents and not only Ft as it relates to sampler collection efficiency, etc.

The other critical point to bring up related to this is based on basic industrial hygiene practice. DHS OHA should not be claiming that the Ft BARs were associated with trace detections because they have absolutely no way of knowing what was in the environment (airborne) at the time the organism was collected. Most likely, there was a very large aerosol present when it was detected as BioWatch requires large concentrations to be present. I believe Stephen has more information on the concentrations that are needed.

Best,
Angie

Document 55

Morse, Stephen A. (CDC/OID/NCEZID)

From: Weber, Angela (CDC/OID/NCEZID)
Sent: Thursday, August 16, 2012 3:03 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Cc: Weber, Angela (CDC/OID/NCEZID); [redacted]
Subject: RE: Trace amounts

Thanks Stephen.

I went through the process below of also estimating the time it would take to inhale a concentration equivalent to the ID50 for Ft as most of the collectors run on a 24-hour period versus a 12-hour period. This is only theoretical of course as it is a number simply based on what can be detected on the filter so lots of caveats are needed around this. Because of all the caveats, I'm glad to see that you recommended only focusing on the analytical portion! Please feel free to share this with Toby. I'm going to pass it along to Steve Papagiotas (copied here) as he works on the response aspects of BioWatch.

One thing I would note is that estimated breathing zone concentrations should not be based on the Ct values reported for a BAR. I could see someone may want to try doing this in a response, but it would be a misuse of data. The primary reason for this is that the BioWatch collectors are area samples that in most all cases are not in the breathing zone of the public. Plus, the Ct value is semi-quantitative at best – when taking into account all the other unknowns involved, the Ct value really is more of a qualitative estimate (e.g., is something there are not? If so, is it a relatively high or low concentration). The idea that 35 is treated as a magical number for the Ft response is concerning and all involved should realize that number was simply picked as no Ct values for Ft were found lower than this and no one has gotten sick at the levels that had been reported. This would be important to bring up with DPEI, so in the case BioWatch ever detects a true BAR, the appropriate interpretation of the data can be made. Additionally, what shows up on the filter is only a fraction of what was in the air during the sampling period due to the poor collection efficiency of the collector as well as all the air that passes around the filter (it leaks, but because the appropriate studies have not been done, we don't know how much it leaks). *So...a Ct value for any of the agents is a true guess and should not, under any circumstances, be used to estimate an exposure dose or to determine what area was involved in the release that had sufficient concentrations that would result in an infection.*

Another caveat to add regarding the sampling volume (in calculations below) is that I went ahead and assumed a collection flow rate of 100 lpm. I noted, however, in the BioWatch programs "BioWatch Field Operations SOP" that they are only using secondary calibration devices (instead of primary), only calibrating once a quarter (should be done before and after every sample but I'm guessing this would be too labor intensive for them), and flow rates must be adjusted based on barometric pressure and temperature (another reason it must be done every day – as you can imagine, the temperature fluctuations over 3 months). None of this is mentioned in their SOP so my guess is that if trained personnel (e.g., industrial hygienists) went out and calibrated a portion of the PSUs out there (including those in Denver for example so you could see if they were adjusting for higher altitudes), I would think you would find quite a variation in the operational flow rate of the PSUs currently in use. This is another reason for treating the Ct values as only qualitative – who knows how much air is actually being collected from day to day. *Another concern this brings up is lowering the cut-off Ct value for Ft to get around the analytical problems and false positives. In doing so, you are making the assay even less sensitive when already the LOD is very high at around $2.4x10^5$ organisms (this is not a trace level as claimed by DHS).*

[redacted]

[redacted]

Thanks for sharing the below,
Angie

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Friday, August 03, 2012 5:05 PM
To: Weber, Angela (CDC/OID/NCEZID)
Subject: FW: Trace amounts

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, August 01, 2012 1:46 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Trace amounts

Hi Toby,

[redacted]

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, August 01, 2012 1:22 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Cc: [redacted] Holmes, Harvey T. (CDC/OID/NCEZID); Chaltram, Jasmine (CDC/OID/NCEZID)
Subject: FW: Trace amounts

Stephen,

Thanks for taking the lead in drafting this. The numbers of bacteria on a filter (approximately 2.4 and 10^5) are in the same range as numbers provided independently by Harvey, and this does make sense.

What seems to be important is not just the number on the filter, but the number of cells per unit volume of air sampled. I don't know enough about the BioWatch system to know the average amount of air sampled per filter. Do you? Can we calculate the number of bacteria per ml of air? We know the average volume of air that an adult inspires per minute. From all of this, someone would need to calculate how many minutes of exposure to the air with the bacteria would give a LD_{50}. If would take a long exposure to get an LD_{50}, that would sound like a trace amount. If it would take a very short exposure to get an LD_{50} that would not sound like a trace amount.

A lot of this is really respiratory toxicology kind of work. Maybe we just need to stop at the number of bacteria on the filter, and let others determine how that relates to air infectivity?

Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Monday, July 30, 2012 8:56 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: [redacted]
Subject: Trace amounts

Hi Toby,

I took a crack at addressing the question concerning what is meant by "trace amounts." Feel free to comment.

Thanks,
Stephen

What is meant by trace amounts?

Trace amounts have been described as a BAR with a high C_T value (ca. 40). However, that does not give one a feel for how many organisms are actually present on the filter that when analyzed result in a high C_T value. In order to understand this, I have performed the following calculations:

1. Only ¼ of the filter is used for extraction (x4);
2. Nucleic acid extraction efficiency is, at best, ca. 1% using bead beating (x100) (it's probably closer to 0.1%);
3. Final elution volume is 150µl of nucleic acid extract of which 5µl is analyzed/reaction (x30);
4. RT PCR sensitivity is about 20 organisms/reaction.

Therefore, a positive result would require:

20 x 30 x 100 x 4 = 240,000 organisms (or 2.4×10^5 cells) on a filter just to get a positive result at the cutoff. This is not a trace amount of a pathogen. For example, the ID_{50} for *F. tularensis* is 10 – 50 organisms. However, it indicates that false negative results remain problematic with low numbers of agents.

Document 56

[redacted]

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 6:03 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Fw: Question #3 about the LOD summaries

Categories: Red Category

Fyi...

From: Beck, Linda [mailto:linda.beck@hq.dhs.gov]
Sent: Monday, October 22, 2012 05:13 PM
To: Farrell, Michael (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Mike,
Sorry for the delay. I wanted to check with a few folks.

We do not have data that show how the filters and extraction from the filters affects LOD. However:

- We did analysis earlier this calendar year where we made assumptions based on SME input regarding filter extraction efficiency and DNA extraction efficiency and plugged in the assay LODs based on the testing referenced above to calculate Gen-1 / Gen-2 sensitivity. The results are contained in a white paper and briefing that are classified SECRET
- The "Reference System Test" that we are trying to kick off at DPG is designed to measure filter extraction efficiency and DNA extraction efficiency, as well as the entire system's LOD. Unfortunately, this dataset will not be available until Feb 2013 at the earliest.

Looking forward to seeing you tomorrow.
Hope this helps!
Linda

From: Farrell, Michael (CDC/OID/NCEZID) [mailto:mqf2@cdc.gov]
Sent: Monday, October 22, 2012 1:49 PM
To: Beck, Linda; [redacted]
Subject: FW: Question #3 about the LOD summaries

Hi Linda and Kathleen, fyi below in regards to my query.

Mike.

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 1:49 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID); [redacted]
Subject: FW: Question #3 about the LOD summaries

Hi Dr. Merlin – that is true we have not done those studies. I will reach out to the SPO and see what may have been done in this area, perhaps in concert with Gen 3 comparative testing, that might provide some info on the LOD of spiked filters with the current Gen 2 processes.

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 11:34 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Re: Question #3 about the LOD summaries

Mike,
Thanks for the responses. The bottom line is that the summaries we have provided to the committee do NOT provide LOD for the LRN assays on BioWatch filters. Have we done those studies? Do we know how the filters and extRaction from the filters affects LOD? Thx! Toby

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 09:17 AM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Dr. Merlin, some answers below in red in parentheses.

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 7:10 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Question #3 about the LOD summaries

These summaries are about 4 years old and look at 3 instruments and 3 extraction methods. I assume by now virtually all of the labs are using the 7500 dx fast. Are they all using a standard extraction method? (the extraction methods are standardized – a choice of two automatic (Roche), or one manual kit (Qiagen)) Does this make a difference in LOD? (Yes, it can – I would have to see the data) Do we have an extraction recommended for BioWatch filters? (the Biowatch process uses a distinct extraction method amenable to air filters that is not used in the LRN) Thanks! Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 06:32 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: RE: Explanation of discarding data from positive NTC's in analysis of LOD of FT primer/probe set

Second question: What is the reaction volume of the analysis? (25 ul) Is it the same for all instruments? (yes) Is it 10 microliters? (no)

Thx,

Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 6:27 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Explanation of discarding data from positive NTC's in analysis of LOD of FT primer/probe set

Mike or Laura,

It looks like I'm going to have to brief Congressional staff this week on the summaries we provided of the LOD studies. In the Ft summary, we talk about laboratories experiencing problems with positive NTC and we discard those data. NTC is a non template control, right? (yes) What is that exactly? (It is a PCR reaction with all of the ingredients except water replaces actual sample volume. This controls for potential contamination of reagents that might lead to a false positive result) It has not target Ft, so why would a number of sites have problems with positives? (For FT3 assay, the former BioWatch screening assay, we and others through 3rd party testing have observed an underlying NTC reactivity of approximately 1 in every 500 reactions. The reason is unknown, however nearly all of these occur at ct values above 40 and was one of the drivers of our decision to change from 45 to 40)

Thanks,

Toby

[redacted]

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 6:03 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Fw: Question #3 about the LOD summaries

Categories: Red Category

Fyi...

From: Beck, Linda [mailto:linda.beck@hq.dhs.gov]
Sent: Monday, October 22, 2012 05:13 PM
To: Farrell, Michael (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Mike,
Sorry for the delay. I wanted to check with a few folks.

We do not have data that show how the filters and extraction from the filters affects LOD. However:

- We did analysis earlier this calendar year where we made assumptions based on SME input regarding filter extraction efficiency and DNA extraction efficiency and plugged in the assay LODs based on the testing referenced above to calculate Gen-1 / Gen-2 sensitivity. The results are contained in a white paper and briefing that are classified SECRET
- The "Reference System Test" that we are trying to kick off at DPG is designed to measure filter extraction efficiency and DNA extraction efficiency, as well as the entire system's LOD. Unfortunately, this dataset will not be available until Feb 2013 at the earliest.

Looking forward to seeing you tomorrow.
Hope this helps!
Linda

From: Farrell, Michael (CDC/OID/NCEZID) [mailto:mqf2@cdc.gov]
Sent: Monday, October 22, 2012 1:49 PM
To: Beck, Linda; [redacted]
Subject: FW: Question #3 about the LOD summaries

Hi Linda and Kathleen, fyi below in regards to my query

Mike.

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 1:49 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID); [redacted]
Subject: FW: Question #3 about the LOD summaries

Hi Dr. Merlin – that is true we have not done those studies. I will reach out to the SPO and see what may have been done in this area, perhaps in concert with Gen 3 comparative testing, that might provide some info on the LOD of spiked filters with the current Gen 2 processes.

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 11:34 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Re: Question #3 about the LOD summaries

Mike,
Thanks for the responses. The bottom line is that the summaries we have provided to the committee do NOT provide LOD for the LRN assays on BioWatch filters. Have we done those studies? Do we know how the filters and extRaction from the filters affects LOD? Thx! Toby

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 09:17 AM
To: Merlin, Toby (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Dr. Merlin, some answers below in red in parentheses.

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 7:10 AM
To: Farrell, Michael (CDC/OID/NCEZID); [redacted]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Question #3 about the LOD summaries

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Subject: Explanation of discarding data from positive NTC's in analysis of LOD of FT primer/probe set

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Thanks,

Toby

Document 57

PETER T. KING, NEW YORK
CHAIRMAN

BENNIE G. THOMPSON, MISSISSIPPI
RANKING MEMBER

One Hundred Twelfth Congress
U.S. House of Representatives
Committee on Homeland Security
Washington, DC 20515

July 9, 2012

The Honorable Janet Napolitano
Secretary
U.S. Department of Homeland Security
301 7th Street SW- Mail Stop 0020
Washington, DC 20528

Dear Secretary Napolitano:

I am writing to express my continuing concern regarding the Department of Homeland Security's BioWatch program and to request a copy of an analysis conducted by the Department in January, which, according to a July 8, 2012 article in the *Los Angeles Times*, found significant failures in the BioWatch Generation-3 technology.[1]

Since its inception, I have raised serious questions regarding the BioWatch program's cost, the efficacy of BioWatch technology, and whether the technology is responsive to current threat assessments. Over the last decade, approximately $800 million has been invested in developing BioWatch technology. Democratic Members of this Committee have raised questions about the accuracy of the readings produced by the currently deployed generations of BioWatch technology and delays in the development of BioWatch Generation-3. In response, the Department has told Members that current BioWatch technologies will prevent needless deaths and that the development of the next-generation technology is on track. The *Los Angeles Times* story, however, calls these statements into question and notes that one State health official has called BioWatch "a colossal waste of money."[2]

The *Los Angeles Times* reports that federal agencies have documented 56 BioWatch false alarms in cities using the currently deployed technology. Due to the high number of false alarms, reports indicate that State and local health officials have relatively little confidence in the technology. Moreover, this lack of confidence seems to be shared at the Federal level. Officials at the Centers for Disease Control and Prevention have said that they would not begin distribution of medications without performing additional tests to confirm the BioWatch result, thereby undermining any therapeutic benefits anticipated as a result of an advanced warning system.

[1] David Willman, "The Biodefender that Cries Wolf," *Los Angeles Times*, at A1 (July 8, 2012).
[2] *Id.*

Thank you for your attention to this matter. Should you have any questions or require additional information, please contact Cherri Branson, Chief Counsel of Oversight, Committee on Homeland Security, at (202) 226-2616.

Sincerely,

Bennie G. Thompson
Ranking Member