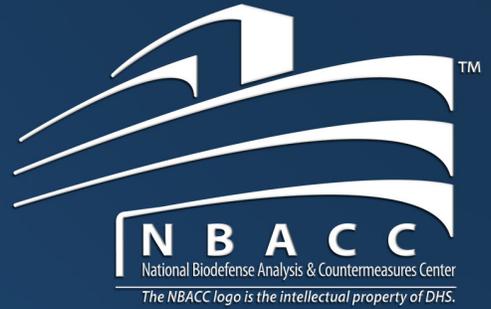




Homeland Security

Science and Technology



STRATEGIC PLAN

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Mission and Vision

Biocrime and bioterror acts continue to occur; natural diseases continue to emerge and challenge the health of naive populations; the life sciences and biotechnologies are moving forward at an unprecedented pace—generating knowledge and new tools for both beneficial and nefarious uses. In short, biological threats are evolving, our need to defend against them is growing, and our approach must reduce risks from specific known threats while providing capabilities that can promptly adapt to, and address, unanticipated threats.

The intended outcomes for the National Biodefense Analysis and

Countermeasures Center (NBACC) are:

- 1) scientific analyses to support biocrime and bioterror attribution investigations;
- 2) timely scientific biological threat characterization analyses to support intelligence assessments, preparedness planning, and response to both events and identified potential threats; and
- 3) a continuously available national capability of broad and adaptable competencies that provide both pre-positioned information and responsive scientific experiments for newly identified threats.

The NBACC mission is to provide the scientific basis for characterization of biological threats and bioforensic analysis to support attribution of their planned or actual use.

Our vision is for the NBACC to be the national security biocontainment laboratory that responds to, and provides data required to support prevention, protection, mitigation, and recovery from, current and future biocrime and bioterrorism threats.

Accomplishments

The Department of Homeland Security (DHS)/NBACC strategy that was laid out in previous plans has been successfully implemented with significant outcomes in bioforensic analysis, threat characterization, and continuously available operations.

The National Bioforensic Analysis Center (NBFAC) component of NBACC has maintained 24/7 availability and completed analyses in support of over 125 Federal Law Enforcement cases. NBFAC has established and provided sensitive and specific agent-based assays for more than 60 human and six animal high-consequence bacteria, viruses, and toxins. To meet law enforcement requirements, NBFAC assays and processes were accredited to an international quality standard (ISO 17025). A new methods-based approach to microbial forensics utilizing nucleic acid sequencing and bioinformatics was developed. This introduced DNA sequencing into the ISO environment, and it has been applied to casework. The NBFAC also trains and provides biocontainment laboratory access to traditional forensic examiners for investigative analyses of biologically contaminated evidence (see Figure 1).

The National Biological Threat Characterization Center (NBTCC) component of NBACC has responded to DHS and other agency requests for scientific evidence to clarify the hazard from specific biological threats and to

improve understanding and confidence in risk assessments for biodefense planning. Data generated have resulted in information required to evaluate the hazards associated with dual-use, commercial off-the-shelf equipment; assess the threat posed by bacterial toxins; determine the potential impact of food contamination scenarios; and provide specific threat characterization data associated with other biodefense scenarios specified by the government. In order to address national biodefense priorities in threat characterization, capabilities were established including those for analyses of agent persistence, inhalation hazard, and virulence.

NBACC provided safe, secure and compliant support to the programs in business and infrastructure operations. A major accomplishment was activation and registration, on a compressed schedule, of over 10,000 square feet of BSL-4 space with transition of scientific and casework support activities from leased space to NBACC laboratories while maintaining safety, security, compliance, operational response capability, and ISO registration. In order to support the transition schedule, the NBACC developed and received regulatory approval for an innovative BSL-4 “swing” BSL-3 approach. The NBACC is currently operating over 21,000 square feet of laboratory space.

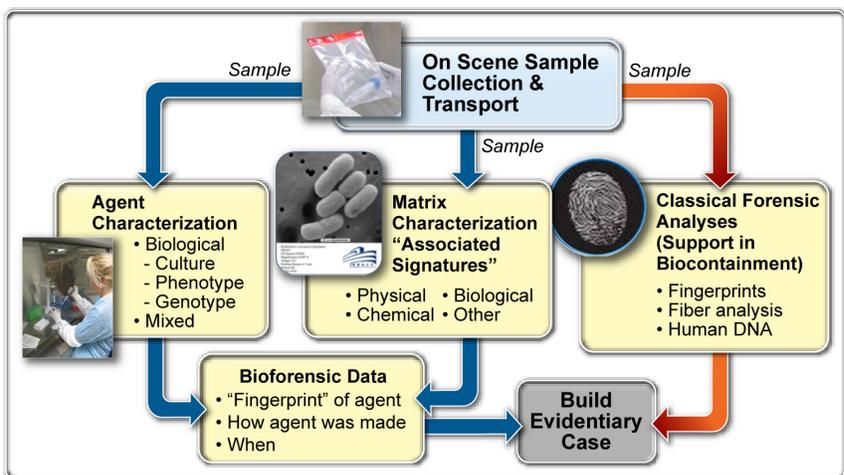


Figure 1: NBACC performs microbial forensic analysis, as well as supports traditional forensics of potentially contaminated evidence.

Capabilities

The DHS, NBACC, and NBACC External Science & Technology Advisory Committee identified capabilities that have established a leadership position compared to other laboratories (see Figure 2). The genomics capability applied to microbial forensics is cutting edge, and is providing a critical new national security capability to allow identification and characterization of any microbial organism, including “unknown” organisms such as emerging, chimeric, or synthetic organisms.

NBACC continues to advance broad capabilities in multiple areas (e.g., bacteriology, virology, toxinology, business operations, and information technologies) to support the DHS mission.

Strategy

Strategic goals target a ten-year planning horizon and are linked to the present through program roadmaps. A key component of the NBACC strategy is balanced implementation of mission, operations, and outreach in order to be a steward of NBACC resources and a responsible partner with our stakeholder communities.

National Biological Threat Characterization Center (NBTC)

The NBTC supports national goals to deter and reduce the impact of current and newly identified biological threats by providing timely scientific data, knowledge products, and expertise that support threat analyses, planning, preparedness, response, and recovery. The NBTC utilizes unique combinations of biocontainment laboratories, instrumentation, and broad scientific competencies to characterize risk-associated attributes of biological agents, biotechnologies, biodefense vulnerabilities, and countermeasure strategies. These capabilities are available to support other analyses of national significance. The two NBTC Strategic Goals are:

SG NBTC-1: Provide timely biological threat characterization data

The NBTC will provide timely biological threat characterization data to reduce the impact of bioterrorist attacks by supporting response, threat analyses, and prioritization in biodefense planning. Response broadly includes timely support to events and hazard assessments

Capability	Status	Intended Strategic Outcome
Genomics/ Bioinformatics	<ul style="list-style-type: none"> • Casework support • First ISO 17025 genomics capability • Computer cluster operational • Algorithm and software development demonstrated • Epigenetic method assessment 	Operational methods-based approach for bioforensic analysis and threat characterization for: <ul style="list-style-type: none"> • Traditional threat agents • Complex samples • Engineered agents/chimera • <i>De novo</i> agents • Production signatures 
Aerobiology	<ul style="list-style-type: none"> • Registered to support hazard analysis associated with BSL-3 and 4 agents 	Characterization of: <ul style="list-style-type: none"> • Risks from commercial dissemination devices • Environmental and agent properties that impact planning and response
Comparative Medicine	<ul style="list-style-type: none"> • BSL-2, 3 & 4, ISO, and GLP experience • ABSL-4/2 space on-line • AAALAC International Accreditation with commendations 	Characterization of virulence, pathogenicity, & other host-associated attributes of threat agents: <ul style="list-style-type: none"> • Support threat assessments • Inform response 
Biocontainment Operations	<ul style="list-style-type: none"> • Maintained continuous operations in leased and NBACC labs • 10,400 sq. ft. registered BSL-4 space with “swing” BSL-3 capability • BSL-4 protocols modified to work safely with bacterial spores 	<ul style="list-style-type: none"> • Assure safe, secure, and compliant biocontainment operations • Nurture an NBACC culture of responsibility • Vacate leased labs on accelerated schedule to meet DoD BRAC requirement 
Quality Management	<ul style="list-style-type: none"> • ISO 17025 for bioforensics maintained continuously for bioforensics since January 2006 through lab transitions • Institutional learning and management process 	<ul style="list-style-type: none"> • Assure high quality results for attribution investigations and other assessments of national significance • Engaged NBACC culture 

Figure 2: NBACC core capabilities with a leadership position.

of adversary-associated methods, technologies, and agents. Scientific threat characterization data also support assessment of vulnerabilities and potential countermeasures. The NBTC will work with stakeholders to organize, pre-process, and pre-position information to be of the greatest utility in event response.

SG NBTC-2: Identify and characterize the biological attributes of any agent

The NBTC will establish and make available broadly-applicable identification and characterization methods required to assess both current and future biological threats. The methods will be available to assess the hazard (e.g., virulence, environmental stability) and potential consequences (e.g., countermeasure effectiveness). Because the number of potential threats is large and the threat will continue to evolve, a component to achieving this strategic goal is to develop a more integrated approach to assessing hazards (e.g., predictive models).

NBTC Roadmap

Implementation of the roadmap shown in Figure 3 transitions NBTC from the current agent-specific, parameter-by-parameter approach to a systems engineering approach that provides

more robust scientific input for planning, response, and threat assessments.

The goal is to have greater operational impact by organizing data so that key threat characterization parameters can be utilized in more predictive and timely science-based estimates. The NBTC will build the initial organization around the five attributes associated with a high-consequence attack (the “attack pathway”) by an adversary: 1) Agent acquisition; 2) Agent production; 3) Dissemination; 4) Virulence; and 5) Availability of effective countermeasures. This approach does not require following every step of the attack pathway in order to sufficiently understand and mitigate risks; and is aligned with the U.S. defensive strategy and compliant with U.S. laws and international treaties.

National Bioforensic Analysis Center (NBFAC)

By Presidential and Homeland Security Directives, the NBFAC is the lead federal facility for technical forensic analysis of materials in support of attribution investigations involving suspected and actual bioterrorism and biocrimes. The NBFAC utilizes state-of-the-art, agent-specific assays and next generation sequencing and bioinformatic capabilities to identify and characterize biological threat agents in high containment

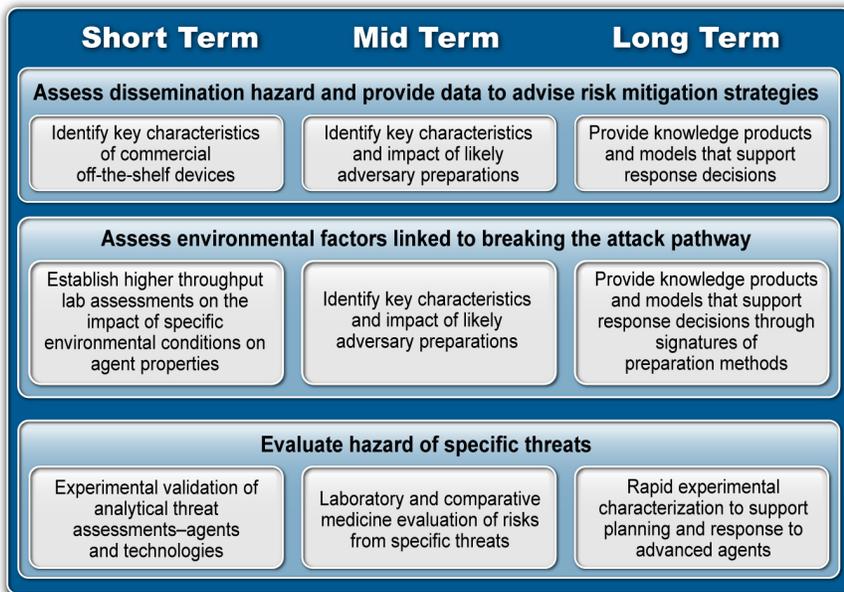


Figure 3: The National Biological Threat Characterization Center (NBACC) Roadmap

laboratories specifically designed to support bioforensic analyses. The capabilities developed for law enforcement support are available to support other national priorities. The three NBFAC Strategic Goals are:

SG NBFAC-1: 24/7 availability to support casework

The NBFAC will maintain 24/7 operational availability to support attribution investigations. Operations will be conducted according to internationally-recognized standards using an ISO 17025 registered quality management program. New casework capabilities will be transitioned into the ISO program as they are established.

SG NBFAC-2: Identify and characterize any biological agent in any sample

The NBFAC will build on the recently established genomics-based approach with the strategic goal to identify and characterize any biological agent in any sample including traditional, newly emerging, and engineered biological agents. Achieving this goal will continue to benefit from commercial investment in sequencing technologies. The NBFAC will develop new algorithms for combining data from multiple instruments in order to utilize the advantageous features and overcome the limitations of specific sequencing instruments. The NBFAC will develop, characterize, and integrate across repositories, databases, instruments, chemistries for extraction from complex

matrices, and bioinformatic algorithms to achieve this strategic goal.

SG NBFAC-3: Establish a production deduction capability

Building on our whole genome sequencing infrastructure, the NBFAC will develop and demonstrate an approach to production deduction that takes advantage of epigenetic modifications of bacterial and viral nucleic acids that are associated with different growth conditions, agent preparations, and environmental stresses.

NBFAC Roadmap

The roadmap shown in Figure 4 provides a transition path from “establish”

to “maintain” for several near term objectives. The scientific emphases in the roadmap address mid term and long term objectives to characterize more complex samples and samples that potentially include genetically modified biological agents.

External Sponsor Program (ESP)

DHS designed and supports the NBACC as a special facility and a national capability.

SG ESP-1: Extend the scientific and national security impact of NBACC

NBACC leadership continues to expand engagement with the biodefense community to make NBACC capabilities available. The approach develops ESP projects that utilize the NBACC staff and facilities to execute biodefense research & development for entities external to the DHS Science & Technology Directorate.

SG ESP-2: Support and enhance NBACC competencies, capabilities, and infrastructure

The DHS and NBACC will prioritize ESP project opportunities to achieve this strategic goal.

Capabilities: SG Capabilities-1: Develop, nurture, and make available the capabilities required for current and future mission needs

In addition to the capabilities described previously, the molecular genetics capability will be strengthened over the next several years to support characterization and attribution of enhanced and advanced agents.

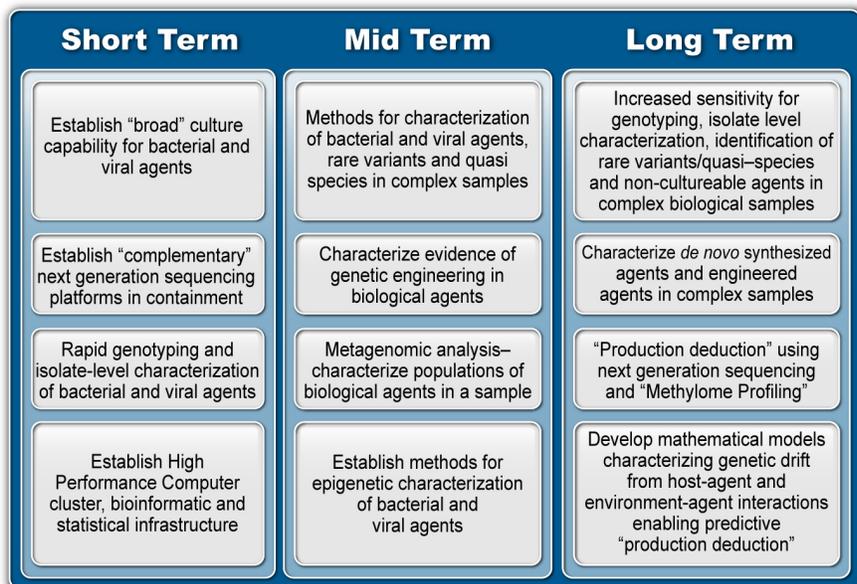


Figure 4: The National Bioforensic Analysis Center (NBFAC) Roadmap

Management and Operations:
SG M&O-1: Provide safe, secure, compliant, and sustainable infrastructure operations to meet mission needs

Accomplishing the NBACC mission requires robust special facility functions and safe, secure, compliant, and sustainable infrastructure operations. The DHS and the BNBI Board of Directors will continue to provide oversight for safety, security, and compliance. The NBACC will utilize communities of practice (e.g., professional societies, DHS S&T Laboratories, Battelle affiliates) to benchmark best practices as well as audits and inspections (e.g., CDC/USDA, AAALAC, Defense Security Service, Nuclear Regulatory Commission) to maintain compliant operations.

General purpose and specialized information technology systems will provide “office” services as well as supporting building automation, laboratory information management, and record management.

SG M&O-2: Nurture a culture of responsibility that is “compliant plus” and an outstanding work environment

The greatest resource at the NBACC is its outstanding staff. Continuously available applied science capabilities require a

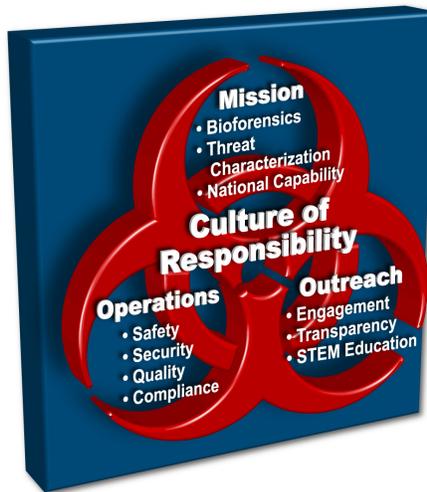


Figure 5: Mission accomplishment requires simultaneous excellence in operations and outreach built upon a culture of responsibility.

work environment that is productive and actively manages the prevention of interruptions caused by errors, accidents, non-compliance, and re-work.

The NBACC will continue to emphasize a culture of responsibility that begins with safety and extends expectations for rule following and human reliability (e.g., identification and remediation of error precursors) to all areas—science, operations, and outreach (Figure 5).

Consistent with a best practice identified by the National Science Advisory Board for Biosecurity, all NBACC projects have an independent biosecurity review before work starts.

Our quality management program will continue to be company-wide, complement the ISO 17025 bioforensics quality program, and include management system reviews to reinforce what works and make adjustments as new approaches are developed and lessons are learned.

SG M&O-3: Provide compliant business practices that enable mission functions

The NBACC will utilize community of practice benchmarking, company governance feedback, and independent audits to identify, implement, and monitor compliant business processes. Business operations will identify and implement the compliant processes that best address mission needs within the resource constraints of a relatively small company. A finance approach that will support ESP is a significant new component of the business practices strategic goal.

Business operations will continue to be linked to the science programs and infrastructure operations through a strong project management group.

Outreach

The NBACC is committed to seeking out diverse perspectives, evaluating and appreciating the basis for differences, and using this input to improve our programs and management practices

SG Outreach-1: Actively participate in the biodefense and scientific communities to extend the impact of the NBACC and improve performance

Formal and informal approaches will be used to maintain strong relationships with the biodefense and scientific communities. Informal approaches will include NBACC staff members serving on committees, panels, and peer reviews for other organizations. Formal approaches to achieve the outreach strategic goal will include:

- Participation in National Interagency Confederation for Biological Research and National Interagency Biodefense Campus activities;

- Utilization of peer review and working groups including an external Science and Technology Advisory Committee;
- Use of the ESP as valuable feedback on current national priorities and the state-of-the-art; and
- External benchmarks of best practices among DHS S&T Laboratories, Battelle-affiliated Communities of Practice, and Department of Energy Laboratories.

SG Outreach-2: Engage with the local community with identifiable positive impacts

As part of engaging the local community, the NBACC commits to dialogue, participation, and service and will continue open, credible, and trusted relationships and communication channels with key stakeholders, including local and national media (Figure 6).



Figure 6: NBACC/BNBI has been recognized for the quality of its work place/work force and education volunteerism and philanthropy.



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This Document was prepared for the Department of Homeland Security (DHS) by the Battelle National Biodefense Institute, LLC (BNBI) as part of contract HSHQDC-07-C-00020 to manage and operate the National Biodefense Analysis and Countermeasures Center (NBACC), a Federally Funded Research and Development Center. In no event shall the DHS, BNBI or NBACC have any responsibility or liability for any use, misuse, inability to use, or reliance upon the information contained herein. **In addition, no warranty of fitness for a particular purpose, merchantability, accuracy or adequacy is provided regarding the contents of this document.**