

**U.S. House of Representatives
Committee on Homeland Security
Subcommittee on Emergency Preparedness, Response, and Communications**

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April 13, 2011**

Introduction

Good afternoon, Chairman Bilirakis, Ranking Member Richardson and distinguished Members of the Subcommittee. It is an honor to appear before you today. In fulfilling the Department of Homeland Security's (DHS) mission to protect the American people, the Science and Technology Directorate (S&T) strives to equip decisionmakers with tools for better assessing the significant risks that chemical, biological, radiological, and nuclear (CBRN) threats pose to the nation. In my statement today, I intend to discuss the utilization of the DHS S&T's Risk Assessment and Material Threat Assessment products which support the issuance of the Material Threat Determinations (MTD) that inform the federal government's medical countermeasure decisions.

On July 21, 2004, President George W. Bush signed into law the *Project BioShield Act of 2004* (P.L. 108-276) (BioShield). The purpose of BioShield is to accelerate and encourage the research, development, acquisition, and availability of safe and effective medical countermeasures to protect the U.S. from CBRN threats. In 2004 Congress appropriated \$5.6 billion for a Special Reserve Fund for use over 10 years (FY04-FY13) to acquire those medical countermeasures. Section 3(a)(2) of BioShield, adding section 319F-2(c)(2) to the Public Health Service Act, requires the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services (HHS) and the heads of other agencies as appropriate, to make determinations of CBRN agents that are material threats to the U.S. population. Section 319F-2(c)(2)(B) authorizes the Secretary of HHS to determine the public health consequences and recommend countermeasures to such threats. If suitable countermeasures do not already exist, this process can culminate in a joint DHS-HHS recommendation to the President or his delegate, the Director of the Office of Management and Budget, to authorize the use of BioShield special reserve funds.

To determine the most effective ways to mitigate the effects of CBRN threats or incidents, it is essential to understand that the threat classes (i.e., chemical, biological, radiological, and nuclear) are distinct in their feasibility, likelihood of use, and potential public health consequences. The BioShield medical countermeasure acquisition strategy must be driven by many factors, including threat agents' potential to cause a public health emergency affecting national security and the potential for effective, feasible, and pragmatic medical intervention to counter their effects. Thus, the first step in the BioShield process is determining the relative risks of specific CBRN agents. DHS conducts quantitative Terrorism Risk Assessments (TRAs) of biological, chemical, radiological, and nuclear attacks to better understand the likelihood and

associated consequences of specific types of CBRN terrorist attacks. The TRAs accomplish this by integrating the information derived from the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. The assessments establish the relative risk associated with specific chemical, biological, radiological, and nuclear agents and assist with understanding which agents pose relatively higher or lower threats to the American public. “High risk” agents are then subjected to a secondary, detailed analysis called the Material Threat Assessment (MTA) to support DHS issuance of MTDs in collaboration with HHS.

Summary of Terrorism Risk Assessment Process

Under Homeland Security Presidential Directives (HSPD) 10, 22, and 18, DHS is mandated to conduct the Biological Terrorism Risk Assessment, the Chemical Terrorism Risk Assessment, the Radiological and Nuclear Terrorism Risk Assessment, and the Integrated CBRN Terrorism Risk Assessment.

Federal agency stakeholders provide input on the scope of each TRA by participating in the Terrorism Risk Assessment Working Groups. These recommendations form the basis of each assessment’s models, methodology and improvements. DHS has conducted biennial TRAs since 2006 and each updated assessment includes refinements to the methodology and technical approach that are guided by input obtained from HHS, DoD, EPA, the intelligence agencies and other federal agencies and stakeholders, as well as the National Academy of Sciences.

Once federal agency stakeholder inputs are established, the next phase of the process involves refining the assessments through stakeholder coordination. This phase begins with the elicitation of intelligence from the law enforcement community on threats, including adversary group types and weaponization preferences. Each assessment incorporates a broad set of scenarios that consider multiple routes of exposure, multiple targets, different dissemination approaches and scales of attack, and modeling data from sources across government, academic, and private sectors. These results are then shared with the inter- and intra-agency stakeholders in a draft report for review and comment.

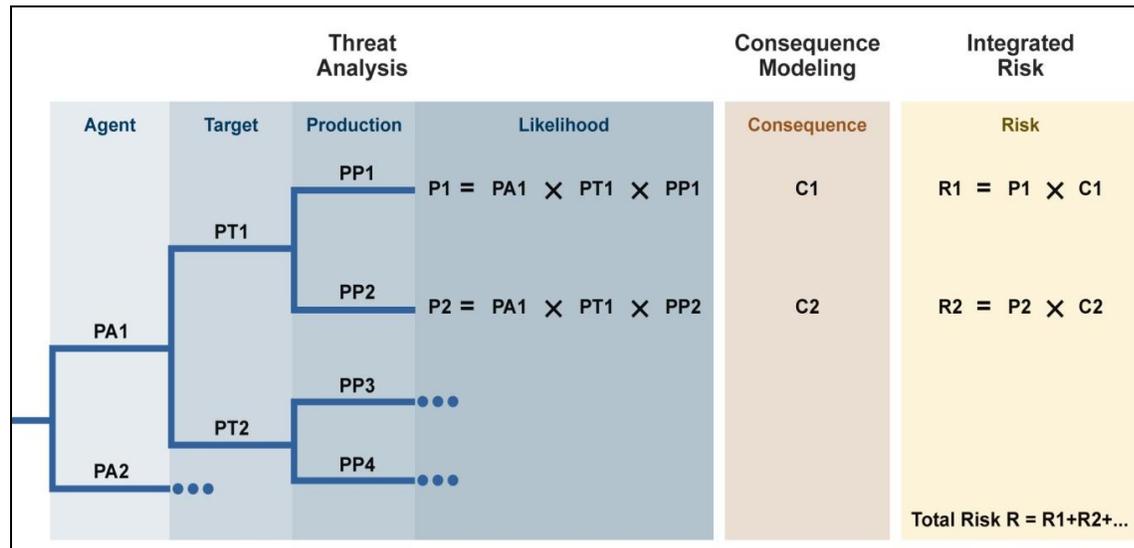
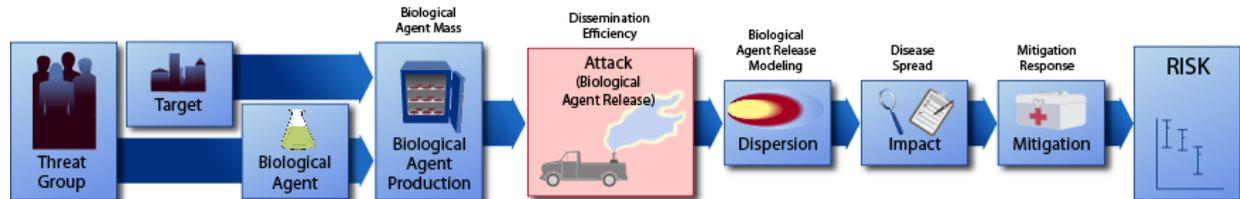
After inter- and intra-agency reviews have been conducted and input incorporated, the final TRA reports are released to the National Security Staff and interagency stakeholders. The Risk Assessments address HHS planning requirements by identifying top-tier CBRN agents (i.e. relative risk ranking where risk is the likelihood of an attack combined with the associated consequences) that pose a high risk to the nation. These Risk Assessments are then leveraged to support the conduct of MTAs on high-risk agents. Results of the MTAs are a critical element of consideration in issuing an MTD.

DHS Terrorism Risk Assessment Products

Biological Terrorism Risk Assessment (BTRA): To inform decisions about biodefense investments, DHS S&T performs the BTRA every two years. The BTRA is a comprehensive, probabilistic risk assessment that integrates the judgments of the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. The BTRA is a strategic level assessment designed to 1) aide in identifying and prioritizing credible, high impact threats, 2) aid in identifying and prioritizing vulnerabilities and

knowledge gaps, and 3) provide a systematic, science-based, common framework for “what if” analyses.

Figure 1. Overview of BTRA Modeling Tool



The probabilistic risk assessment methodology captures the scenarios in an event tree format allowing the model to address different classes of agents, including a full spectrum of attack scenarios, beginning with the relevant characteristics of the adversary groups under consideration, and ending with the effectiveness of the response. In the simple example above, the terrorist enters the event tree on the left hand side with attack conception. The first branch in this simple binary example is the selection of the bioagent. The tree then splits and the second event is the selection of the target, followed by production and dissemination, etc. The accumulation of all steps in the sequence defines a scenario, with a total relative probability defined by the product of the all of the branch probabilities. For each scenario, an estimate of the overall consequence is made. The risk from each branch is then determined as the probability times the consequences, and the total risk is the sum of the risks of all of the branches. Of course, for the branches in which the terrorist fails, there are no consequences and therefore the risk is zero.

The event tree in the 2010 BTRA has 21 events and multiple branches at each event level. The 2010 study scope considers four terrorist types (international, state-sponsored, domestic, lone wolf) exploiting 43 different bioagents (38 human, five livestock pathogens) that may be obtained from two locations (foreign and domestic) by five routes of acquisition (among them theft and environmental isolation). The adversary may use multiple methods of production and

weaponization to attack any of 20 different targets (including a subway, stadium, transportation or outdoor events) using eight modes of dissemination (food, aerosol, etc.). Human health and economic consequences are then calculated for each scenario path in the event tree and combined with probabilities to estimate the risk associated with millions of enumerated scenarios. This enables a comprehensive evaluation of not only what is possible but also probable in bioterrorism. The study model allows for risk data visualization by agent, target, adversary group and other factors to inform understanding. The probabilistic risk assessment methodology also supports an evaluation of the impact of knowledge gaps and incorporates explicit consideration of the inherent uncertainty in bioterrorism modeling.

Chemical Terrorism Risk Assessment (CTRA): The CTRA provides a comprehensive analysis of the homeland security risks from a broad range of chemical threat agent materials, including toxic industrial chemicals, traditional chemical warfare agents, and emerging threats. The CTRA, developed by S&T's Chemical Security Analysis Center (CSAC), uses information from across the Intelligence Community, the Law Enforcement community, and technical experts from the government and chemical industries to assess the capabilities and intentions of different types of terrorist groups, and the feasibility of acquiring a given chemical threat material. Multiple federal agencies are involved in providing information on medical consequences of these attacks, and the capabilities that are available to mitigate the effects of an attack. Using scientific information and advanced modeling capabilities, the consequences of possible chemical attack scenarios are calculated, providing information on the numbers of people likely to be killed or injured in the attacks.

The final estimates of overall risk produced by the assessment combine the likelihood of each attack scenario, the possibility of law enforcement interdiction, and the magnitude of the consequences for each attack. The 2010 CTRA provides a relative risk assessment of 100 representative chemicals for three routes of exposure (inhalation, dermal, ingestion) over 30 different scenario types. This relative assessment of the chemical risk captures the broad range of threats posed by a number of classes of chemical compounds.

CSAC is applying the same probabilistic methodology to assess the risks of chemicals regulated under the Chemical Facility Antiterrorism Standards. This assessment, termed the Chemical Infrastructure Risk Assessment, provides DHS with tools to understand the risk of a chemical release from chemical facilities or while in transport, and to determine the impact of current threat reduction activities.

Radiological and Nuclear Terrorism Risk Assessment (RNTRA): A collaborative effort led by S&T and Domestic Nuclear Detection Office (DNDO), the RNTRA assessment is updated biennially with information from the Intelligence Community, coordinated by the DHS Office of Intelligence and Analysis, and the interagency contributions from the Department of Energy, Nuclear Regulatory Commission, HHS, the Department of Defense (DoD), the Environmental Protection Agency (EPA), and many other federal agencies. The RNTRA includes over 2 million attack scenarios from the highest consequence to most plausible. These scenarios consider: international and domestic terrorist groups as well as lone wolf scenarios; 11 radiological agents and three sizes of improvised nuclear devices; multiple modes of radiological agent dissemination; and many plausible targets such as public entertainment venues, transportation targets and supply chain networks. The scenarios are coupled with analyzing the

public health response, management and distribution of medical countermeasures and resultant fatalities, illnesses and economic consequences using integrated dispersion modeling and national laboratory nuclear effects modeling. This assessment provides decision makers with an understanding of radiological and nuclear terrorism risks as they relate to illnesses and injuries, fatalities, latent cancer morbidities and mortalities and economic cost from both regional and national perspectives.

Integrated CBRN Terrorism Risk Assessment (ITRA): The ITRA is the only federal report that provides an assessment of the relative risks associated with chemical, biological, radiological, and nuclear terrorism in the homeland. The assessment is conducted biennially and provided to the Executive Office of the President's National Security Staff as mandated by HSPD-18. While the purpose of the ITRA intended by HSPD-18 is to inform resource allocation for medical countermeasures, the assessment can be leveraged by a broader range of Federal decision makers to support development of risk management strategies that have tangible operational impact on WMD terrorism risk such as prevention, protection, surveillance and detection, response and recovery activities. The ITRA capability is based on integration and harmonization of each of the threat agent specific assessments (BTRA, CTRA and RNTRA) augmented with intelligence information that establishes the relative likelihood that a terrorist will select a biological, chemical, radiological or nuclear weapon. The ITRA encompasses more than 10 million attack scenarios across broad ranges of consequence and likelihood. They include various terrorist organizations, more than 150 specific agents, multiple modes of agent dissemination, and many potential targets such as public entertainment venues, transportation targets and certain supply chain networks. These types of scenarios are coupled with modeling of the public health response, management and distribution of medical countermeasures to arrive at an estimated risk of fatalities, illnesses and economic consequences associated with attack scenarios.

Federal, state and local agencies can leverage these assessments to guide their WMD defense related investments focused on prevention, protection, surveillance, detection, response and recovery related preparedness efforts. This includes guiding prioritization, development, acquisition and maintenance of medical countermeasures. The assessments are accomplished through formal DHS working groups, where DHS engages with HHS, DoD, the national intelligence agencies, and several other federal agencies such as EPA and NRC. This approach includes several steps in which working group members engage with DHS to develop requirements, provide technical input and conduct a critical review of the TRAs.

Material Threat Assessment Process

The first step in the BioShield process is threat identification and prioritization in order to inform medical countermeasure development and acquisition. DHS has the lead in threat identification and leverages the DHS Integrated Terrorism Risk Assessment findings to determine which CBRN agents present a greater risk based on the relative risk ranking against the U.S. population sufficient to affect national security. Specifically, for the highest ranked agents in the TRA, DHS evaluates the intelligence and threat information and develops and models a highly plausible consequence scenario taking into account acquisition, production, dissemination efficacy, source strength and meteorological conditions. This model is used to derive an estimate of the number of potentially exposed individuals at various levels of exposure, which becomes

part of the MTA. The estimates are provided to HHS, which conducts its Public Health Consequence Modeling (PHCM) as the basis for determining public health impacts. At the conclusion of these studies, a meeting between DHS and HHS takes place to collectively determine the potential impact on public health and its potential to affect national security. If the PHCM results indicate that a significant number of fatalities will result from the highly plausible scenario with a particular agent, it is deemed a “threat” and the DHS Under Secretary of Science and Technology recommends to the DHS Secretary the issuance of an MTD, as outlined in Figure 2. Although the predominant role of DHS in the initial stages of the BioShield process is in conducting the MTAs, assessing the findings of the PHCM and issuing MTDs, DHS is actively involved in the subsequent interagency process and has the joint statutory responsibility with HHS in recommending to the Office of Management and Budget (OMB) to release the BioShield Special Reserve Funds.

For agents considered to be a material threat, HHS determines whether these agents lack an existing, effective countermeasure and whether a countermeasure should be procured using BioShield reserve funds. If so, then HHS uses the interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), created by HHS in 2006, to define countermeasure requirements and acquisition options. The PHEMCE is overseen by an Enterprise Senior Council (ESC), previously known as the Enterprise Governance Board, to take a more integrated, systematic end-to-end approach to the medical countermeasure mission, including research, development, acquisition, storage, maintenance, deployment and guidance for utilization. Currently, the ESC serves as the primary conduit for communication among entities involved in the medical countermeasure mission and coordinates the implementation not only of BioShield, but also: HSPDs 18 and 22; the National Pandemic Influenza Strategy; the Strategic Plan for Countermeasure Research, Development, and Procurement required by the Pandemic and All-Hazards Preparedness Act; and other strategic planning documents. The DHS Office of Health Affairs and S&T are both members of the ESC. To date, DHS has issued 12 MTDs for biological agents, one MTD for radiological materials, and one MTD for nuclear detonation effects.

Figure 2. Process for Risk Assessments through Issuance of a MTD

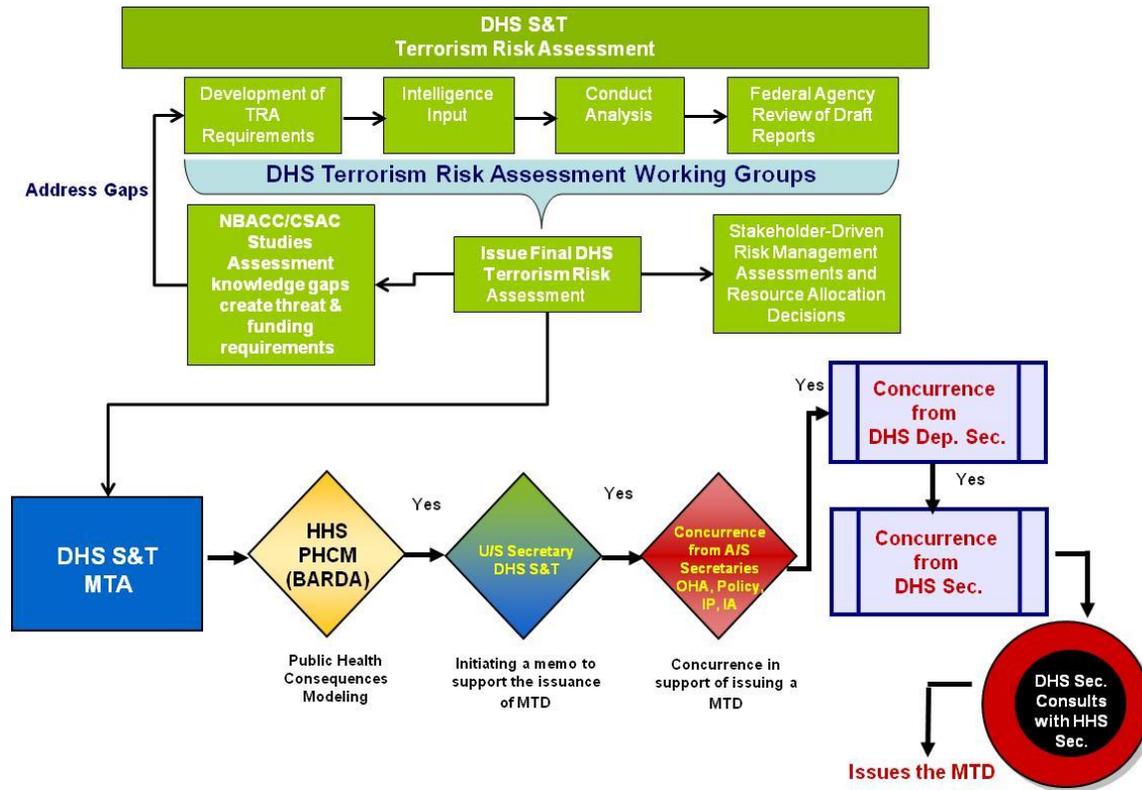
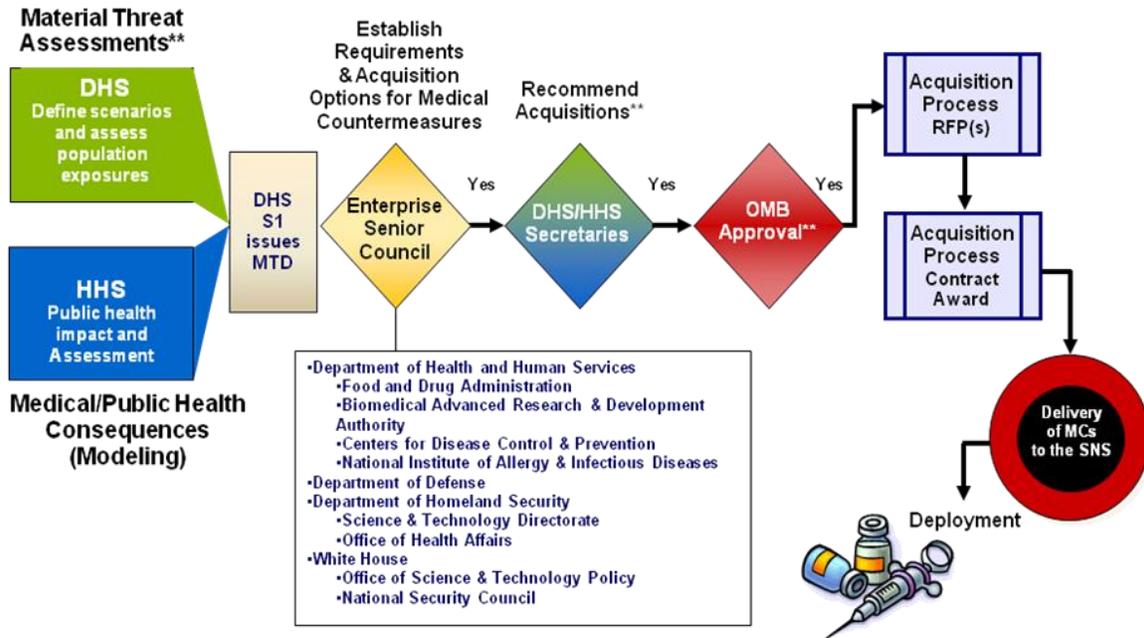


Figure 3. Project BioShield Acquisition Process



** Statutory requirements as defined in The Project BioShield Act of 2004 (P.L. 108-276)
Ref: Department of Health and Human Services

TRA Improvement on Process and Methodology Limitations Identified through the National Academies Report and Stakeholder Feedback

Since their origin, the DHS Risk Assessment Programs have been very proactive in soliciting internal and external expert review of methodology, data inputs, outputs and findings. Characterization of the biothreat and bioterrorism risk is an inherently dynamic problem. DHS is committed to continual improvement of the Terrorism Risk Assessments to support stakeholder decision making. The main challenges we face in evaluating the WMD terrorism risk are that we must rely on historical data and information about our adversaries' future plans – both of which are limited. DHS continues to work closely with HHS, DoD, EPA, and other stakeholders to provide transparency and to address, document, codify and implement requirements aimed to improve the technical quality and utility of the TRAs.

As the first Biological Terrorism Risk Assessment represented the pioneer of the TRAs, it garnered much attention. In response to the DHS-commissioned 2008 National Academy of Sciences (NAS) Report: *“Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change”*, the National Research Council provided 13 recommendations. S&T was able to take action on several NAS recommendations in 2008, addressed others in the 2010 BTRA, and has research dollars invested to address the longer-term challenges, such as modeling the intelligent, adaptive adversary. Since 2006, BTRA has improved in its lexicon, transparency, and external peer review; the scope of consequences considered; platform flexibility; validation and verification; normalization methodology; communication strategy; and overall approach.

The BTRA program has been pushing forward on improvements as quickly as science allows, and the process remains committed to addressing any and all deficiencies noted in the report. Meanwhile, the scientific community continues to debate the evolving new science of terrorism risk assessment and S&T continues to research new approaches. It is clear that providing sound risk-informed guidance to our leadership is a job that is too important not to get right. The models are continually reviewed, updated, and exercised to support partner decision making, and by doing so, DHS adds significant value to the biodefense decision and policy development national dialog.

Informing Current Biological Defense Research and the Value of Knowledge Products

In order to enable our TRAs and MTAs to achieve greater fidelity, the National Biodefense Analysis and Countermeasures Center (NBACC) supports S&T by providing knowledge and understanding of biological agents, closing the knowledge gaps on those known agents, and supporting attribution. The direction and prioritization of NBACC's scientific research are informed by DHS in coordination with interagency partners who serve on our science advisory groups. Reducing the uncertainty in the BTRA is an important target outcome of NBACC's work.

In the current fiscal year, DHS's priority for the National Biological Threat Characterization Center (NBTCC) within NBACC is to develop plans for assessing and reducing knowledge gaps for traditional/nontraditional threat agents. These include specific and/or general properties associated with acquisition, production, dissemination, stability, virulence and pathogenesis, and medical countermeasure efficacy.

Conclusion

Thank you for the opportunity to discuss DHS's S&T Risk Assessment products and the Material Threat Assessment products which support the Material Threat Determinations that inform medical countermeasure decisions.

Characterizing CBRN agents and terrorism risk is an inherently dynamic and challenging problem. As the threat space evolves, so do technical approaches; by continually updating and gathering new data and feedback on the TRAs and MTAs, we ensure that the assessments are backed by the best available science, and that risk reduction strategies are continually re-evaluated to support program effectiveness. DHS is committed to the continual improvement of risk assessments to support stakeholder decision making, investments, and strategic planning initiatives. It is vital to appropriately capture the CBRN terrorism landscape to help prioritize resources and indicate areas which may need additional focus.

Thank you for inviting me to appear before you today. I look forward to answering any questions you may have.