

DHS S&T Technical Review of NRC Draft Report “*Department of Homeland Security’s Biological Risk Analysis: A Call for Change*”

NOTE – this technical review describes a draft version of the NRC report provided to DHS in January of 2008. The final report may be formatted differently causing page references and other references to the NRC report to be inconsistent. DHS will prepare an updated version of this document upon release of the final NRC report on 26 September 2008.

Introduction and DHS Response Overview

The Science and Technology Directorate (S&T) within the Department of Homeland Security (DHS) has received the report authored by the National Research Council (NRC) Committee on Methodological Improvements to the Department of Homeland Security’s Biological Agent Risk Analysis. Entitled “Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change”, this report was provided to DHS S&T for the purposes of formal security review of the document prior to NRC publication. S&T protocol for security review calls for the technical originators of the content to provide first line security review, followed by S&T security officials and senior leadership.

During the security review however, S&T staff observed significant scientific and factual inaccuracies underpinning NRC Final Report recommendations. This document and a number of enclosures accompany the security review findings transmitted to National Academies’ security officials to provide NRC with an opportunity to be made aware of these inaccuracies, which may impact the NRC Report conclusions. DHS is willing to work with the Academies and the NRC to ensure that a thorough and accurate report is published as quickly as possible.

Upon review of the 13 recommendations contained in the NRC Committee’s final report, over a third of them relate to the scope of the analysis. This is in contrast to the Committee’s 6-point charge¹ which focuses exclusively on methodology. Because many of these scope-related recommendations form the basis of some fundamental conclusions (as detailed below), DHS has significant concerns as to why the scope, as laid out by the White House Homeland Security Council (HSC) in Presidential Directives and other documents, is the target of so much of the Committee’s activity. The scope of DHS assessments as well as associated requirements for presentation of data and conclusions, as prescribed by the President, are not readily actionable by DHS S&T, and are far afield from their charge of methodology review.

S&T observed that many of the key recommendations in the Final Report are unchanged, or are minor expansions of the recommendations found in the NRC’s Interim Report

¹ NRC Committee on Methodological Improvements to the Department of Homeland Security’s Biological Agent Risk Analysis. “DRAFT: Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change.” Washington, D.C.: National Academies Press, 2008. Pages ES-3, 1-11.

from this Committee, entitled “Interim Report on Methodological Improvements to the Department of Homeland Security’s Biological Agent Risk Analysis,” published formally on the NRC website in early 2007. These recommendations focused on the need for a clear statement of purpose for the risk analysis, an improved analysis of the “intelligent adversary,” and an increased emphasis on risk management. Many of these recommendations in the Interim Report, and the key points that support them appear in the NRC Final Report as well. DHS finds the majority of the Interim Report and Final Report conclusions to be actionable and technically supported; in fact, several have already been implemented in the 2008 Bioterrorism Risk Assessment (BTRA). Many of the longer range recommendations, such as the recommended need to explore additional models and methodologies are planned for consideration starting in FY09. Ultimately, DHS S&T’s overall understanding of the summary conclusions from the Interim Report are that the “current methodology is adequate but incomplete”² and that the DHS “implementation...appears, for the most part, to be consistent with well-accepted practice in other fields of risk analysis...”³, statements with which DHS agrees.

In stark contrast to the Interim Report findings, the Committee makes a sweeping recommendation captured in Recommendation #13 and its surrounding text in the Final Report, indicating that “...the BTRA in its present form should not be used to assess the risk of bioterrorism threats”⁴ and that “BTRA should not be used as a basis for decision making until the deficiencies noted in this report have been addressed and corrected.”⁵ Despite the similarity of the insights and recommendations between the NRC Committee Interim and Final Reports, the major departure in overall conclusions in the Final Report is explained by the Committee to be underpinned by two factors: “...the reasons noted in Recommendations 2, 4, 10, and 11, which are further detailed in [the] report”⁶ as well as “...mathematical errors, risk assessment modeling mistakes, shortcomings in presentation, and other weaknesses...”⁷. Later in the Final Report, the Committee further explains the reason for the shift: “It was only after the issuance of its interim report that the committee was provided with a copy of the BTRA 2006 report...This revised and more detailed picture...revealed that PRA, as used in BTRA, is the wrong framework for modeling risks...”⁸

The 2006 BTRA Report was delivered to the key Committee members (including the Chair) responsible for the methodological components of the review (Brown and Parnell, Committee Chair), as well as to the National Academies staff at least three months before

² NRC Committee on Methodological Improvements to the Department of Homeland Security’s Biological Agent Risk Analysis. “Interim Report on Methodological Improvements to the Department of Homeland Security’s Biological Agent Risk Analysis.” Washington, D.C.: National Academies Press, 2007. Page 12.

³ NRC Committee. “Interim Report” Page 1.

⁴ NRC Committee. “DRAFT: A Call for Change” Page ES-11.

⁵ NRC Committee. “DRAFT: A Call for Change” Page ES-12.

⁶ NRC Committee. “DRAFT: A Call for Change” Page ES-11.

⁷ NRC Committee. “DRAFT: A Call for Change” Page ES-4.

⁸ NRC Committee. “DRAFT: A Call for Change” Page 1-9.

the issuance of the Committee's Interim Report, which occurred in early 2007⁹. Further, copies of the 2006 BTRA Report were provided (to Brown and Parnell) as well as dedicated reading time during a contractor site visit in Columbus, Ohio on 3 October 2006. While the Committee's Interim Report may have been in preproduction at this time, the Committee Chair and NAS staff should have reviewed all available material prior to release of the interim report, especially given the starkly different impression the Committee formed, after reading the 2006 BTRA Report.

At this point, the critical question is whether or not the four key recommendations cited by the Committee, and the assertion of widespread mathematical and calculation errors (upon which the major departure from the Interim Report is based) are supported in the NRC Report. The risk assessment results put forth in the 2006 BTRA support a risk-informed approach in how the U.S. Government manages the biodefense challenge, and the NRC's recommendation to discard this analysis in its entirety must be carefully examined. Having thoroughly reviewed the NRC's findings, DHS believes that each of the four key recommendations upon which the NRC's overall conclusion is based are substantially flawed, indicating a potential misunderstanding by the Committee of what was actually done in the 2006 BTRA analysis. It should be noted that a substantial amount of both oral and written communication took place with the Committee. One of these four recommendations (Recommendation #2), indicates that Probabilistic Risk Assessment (PRA) is the "wrong framework" for modeling terrorism risk. This statement is a philosophical assertion about how DHS should not approach the problem. Academic literature and key leaders in the field of risk analysis however, do not necessarily agree that this is true (see Attachment A, Ezell BC, Von Winterfeldt, D immediately following this document). As for the Report's assertions that there are "widespread" mathematical errors, a careful review of the NRC Report revealed only a handful of possible errors. These are in fact not errors at all, but apparently a misunderstanding by the Committee of what was done in the 2006 BTRA. Of all the "errors" the Committee refers to, just one is in fact a mistake (and this error was shown to the Committee in April 2006 to have no effect on the BTRA results, and has long since been corrected for the 2008 BTRA).

DHS review of the NRC Committee's report found significant factual errors regarding the BTRA. DHS has provided the Committee with the 2006 BTRA Report, numerous associated briefings and presentations as well as teleconference calls to clarify the BTRA methodology as best possible to the Committee. This document focuses on the Report's four recommendations (#2, #4, #10, and #11), and the assertion of widespread mathematical errors (as well as their review of the 2006 BTRA Report) as the basis for its departure from Interim Report conclusions in Recommendation #13, and will limit its focus to the validity of those findings.

NRC Committee Recommendation #2

⁹ Security Records indicate that copies were sent to Brown, Parnell (Chair), and NAS Headquarters in Washington DC on 16 October 2006. National Academies Press indicates Interim Report was published in 2007.

*To assess the probabilities of terrorist decisions, DHS should use elicitation techniques and decision-oriented models that explicitly recognize terrorists as intelligent adversaries who observe U.S. defensive preparations and seek to maximize achievement of their own objectives.*¹⁰

Recommendation #2, and its rationale as described in the NRC Report asserts that “DHS should use...decision-oriented models that explicitly recognize terrorists as intelligent adversaries...”¹¹ In the expository text preceding this recommendation in the NRC Report’s Executive Summary, the Committee writes:

“BTRA represents adversarial decisions by probabilities assessed by subject matter experts. However, when dealing with an intelligent, goal-oriented, and resourceful adversary (the terrorist), the exclusive use of subjectively assessed probabilities for terrorist decisions is inappropriate. For decision problems as complex as BTRA, the probability that an adversary will choose a course of action should be an output of analysis, not an input.”¹²

In Chapters 1 and 7, the Committee continues to support Recommendation #2 by stating that “...PRA, as used in the BTRA, is the wrong framework for modeling risks that are inherently dependent on the choices made by intelligent adversaries”¹³ and that “The 2006 BTRA does not consider intelligent adversaries. The BTRA probability assessment of terrorist decisions is independent of the potential consequences of the attack.”¹⁴ Then, in Chapter 7 and Appendix D, the Committee Chair outlines a solely-decision theoretic approach as a method that conveniently “resolves all of the major deficiencies that have been identified in the current BTRA.”^{15,16} Also in Appendix D, the Committee Chair makes the *general methodological claim*, not tied to the actual implementation of event trees and Probabilistic Risk Assessment (PRA) in the BTRA, that the Committee believes there to be “...weaknesses in the use of event trees to model terrorist actions since it does not model the actions of an intelligent adversary”¹⁷, a statement that DHS believes to be an opinion, but one that is not shared by the broader risk analysis community based on a review of the literature and discussions with additional risk analysis experts.

Recommendation #2 and its supporting rationales in the NRC Report have two basic components: (1) *philosophical* components related to the appropriateness of eliciting probabilities and using them as inputs to risk analyses, as well as the utility of using PRA and event trees for terrorism risk analysis applications, and (2) issues related to NRC’s

¹⁰ NRC Committee. “DRAFT: A Call for Change” Page ES-6.

¹¹ NRC Committee. “DRAFT: A Call for Change” Page ES-6.

¹² NRC Committee. “DRAFT: A Call for Change” Pages ES-5,6

¹³ NRC Committee. “DRAFT: A Call for Change” Page 1-9.

¹⁴ NRC Committee. “DRAFT: A Call for Change” Page 7-2.

¹⁵ NRC Committee. “DRAFT: A Call for Change” Page 7-6.

¹⁶ The “Bioterrorism Decision Model” described in the NRC Report Appendix D has been presented by Professor Parnell extensively at national conferences over the last year as the best solution for bioterrorism risk analysis in Homeland Security.

¹⁷ NRC Committee. “DRAFT: A Call for Change” Page D-1.

description of DHS S&T's *implementation* of PRA in the 2006 BTRA, as well as other issues related to Recommendation #2 (such as how subject matter elicited information was handled, and whether it is defensible to divorce attack probabilities from consequences).

First, the philosophical components of the analysis will be addressed. With Recommendation #2 and the related NRC report material cited above serving as part of the foundation for the Committee's overall recommendation to discard the 2006 BTRA analysis, DHS S&T requested a technical note that reviews relevant scholarly literature, and has polled top-tier decision and risk analysis experts to examine the key issues. While DHS does not disagree with large sections of the NRC report exhorting DHS to examine and consider additional models, the polled experts and a review of the relevant literature indicate that assessing probabilities for terrorist decisions as *model inputs* as well as the use of event trees instead of/in addition to decision trees are at best, reasonable approaches, and at worst, are scientifically debatable issues among the community of experts. However, the NRC Report strongly asserts that PRA should not be used for terrorism risk analysis and proposes only decision-theoretic approaches as solutions to the problems in the 2006 BTRA.

Attached with this document is a signed letter by Professor Detlof von Winterfeldt and Dr. Barry Ezell summarizing their findings from their expert polling, as well as their written technical note summarizing key scholarly literature and opinions in the field related to the applicability of PRA in terrorism risk analysis. Again, while Committee suggestions highlighting the utility of additional approaches are well taken, the expert polling and literature review suggest that there is significant scientific debate on these issues, making the Report's ultimate finding that the BTRA should not be used at all, a significant reach beyond the body of current risk analysis research in this area.

The NRC Report advances that "the approach represented by Bioterrorism Decision Model (BDM) resolves all of the major deficiencies that have been identified in the current BTRA"¹⁸, however, experts in the community argue that no one model necessarily solves all problems. Some in fact indicate that an analysis of terrorism risk that did *not* include PRA would have serious shortcomings. Interestingly, despite the Report's assertions that decision analysis approaches are the solution to bioterrorism risk analysis, with the exception of three sentences in Chapter 5 of the NRC report¹⁹, the Committee appears to overlook a simple multi-criteria decision analysis (MCDA) approach executed by DHS as part of the 2006 BTRA in parallel to the more sophisticated PRA. This simple approach was explained in detail in the 2006 BTRA Report – over a span of 58 pages, within Chapters 6 and 7, and Appendix B. This parallel analysis, also mentioned in the 2006 BTRA Executive Report, confirms 75% to 80% of the prioritization results in the PRA. It is interesting to note that the Committee barely mentions the MCDA analysis in its review, given its relevance to the Committee's methodological arguments advocating the superiority of decision analysis approaches.

¹⁸ NRC Committee. "DRAFT: A Call for Change" Page 7-6 and similar language on page D-10.

¹⁹ NRC Committee. "DRAFT: A Call for Change" Page 5-9.

While the expert opinions and reviewed literature at the end of this document do not constitute a full and formal discussion of the issues, they nevertheless highlight that there is significant philosophical debate among top-tier researchers regarding the Report's assertions that a solely decision-theoretic approach is best; one in which probabilities should not be elicited for use as model inputs, both assertions that the Committee claims warrant the exclusion of PRA for terrorism applications. DHS respects the NRC Committee expertise in this area, and in fact DHS S&T is taking steps to investigate and implement many of the Committee's recommended approaches²⁰. Given the diversity of scientific opinion within the risk analysis community, DHS does not see the justification for the Report's recommendations to discard an analysis on these grounds.

With the level of debate in the community, and in the literature reviewed in the technical note below, DHS is quite concerned that the Report has overstated the assertions on PRA, event trees, and the assignment of probabilities to terrorist events; assertions which are then used to advocate discarding the 2006 BTRA in total.

Considering the second component of Recommendation #2, whether or not DHS' *implementation* of PRA is appropriate regarding the issues of the "intelligent adversary" and the elicitation of probabilities, DHS has substantive concerns with the Report on this issue as well. First and foremost is the sweeping claim in the Report that "The 2006 BTRA does not consider intelligent adversaries."²¹ Despite the arguments presented above that provide literature and expert evidence that PRA can be used to model "intelligent adversary" terrorism risk, it is noteworthy to repeat an exchange that occurred during the 10 February 2007 Committee meeting at which DHS (Dr. Steve Bennett, BTRA Program Manager) presented DHS' response to the Interim Report findings, which had just been published. During the discussion of the "intelligent adversary" findings in the Interim Report, the same sentiments raised in the NRC Final Report's Chapter 7 and in Recommendation #2 were raised by Professors Parnell and Brown – that the 2006 BTRA could not model the intelligent adversary, because it relied on fixed probabilities elicited from the intelligence community, and did not explicitly model the terrorists' decision processes. DHS explained that the approach for eliciting probabilities from the intelligence community involved a discussion and synthesis of terrorists' decision processes and objectives, which was considered by the analysts when they provided their judgments. Committee member Stephen Pollock interjected at this point to defend this idea, indicating that it was entirely possible that the intelligence community analyst in fact synthesized the decision process to provide an overall probability of a particular action or choice, factoring in the level of "intelligence" of the adversary in their probabilities. This discussion indicates that there were alternative opinions expressed by the Committee member however they do not appear to be represented in the final report. Instead, the Report states the opposite claim about the BTRA, indicating that "...events of 2006 BTRA represent deliberate decisions made by a terrorist, but they are modeled as random events" suggesting the inaccurate conclusion that DHS did not consider terrorist objectives at all in the probabilities .

²⁰ Several FY09 efforts in decision analysis approaches to bioterrorism and WMD risk are in fact planned and budgeted.

²¹ NRC Committee. "DRAFT: A Call for Change" Page 7-2.

Based on the 10 February 2007 briefing and exchange, as well as from numerous briefings and the 2006 BTRA Report – it should have been communicated that the intelligence community incorporated the intelligence of the adversary as it exists in their judgment. This approach is feasible given the intelligence community has information, although incomplete, on decisions and activities the intelligent adversary *actually makes* – that is, real data that provides insight into the intelligent adversary, and how they behave.

DHS believes the proposed Bioterrorism Decision Model (BDM) in Appendix D, as well as the optimization model presented in Appendix E, model the terrorists decision processes as maximizing consequences - “that an intelligent adversary will attempt to inflict maximum expected damage”²² and that “the decision model we have described would identify the terrorist’s best strategy to maximize the consequences of an attack.”²³ These approaches become worst-case based planning, in which the terrorist adversary is assumed to “know” which actions will produce the highest consequences, actions which are then chosen by the adversary in the decision model. DHS believes this is an unrealistic assumption that the adversary is highly “intelligent” and always knows which actions or choices will result in the highest consequences at the end of the process. Unlike conventional attacks, WMD attacks such as bioterrorism have many complex and often unintuitive steps required to truly maximize consequences. The assumption that the terrorist always knows which choices early in an attack plan will ultimately maximize consequences, does not accurately represent terrorist adversary capabilities. For example, the US Government with its sophisticated consequence modeling developed over the last decade still may not be able to accurately predict attack consequences all of the time. DHS believes that terrorists will not have sophisticated consequence modeling available as input for their decision making. There is no question that terrorist organizations can have very clever personnel. But even the most technically competent terrorist organizations would be unlikely to perform detailed analyses of alternative scenarios at the level of sophistication of the BTRA models. Furthermore, the objectives of the organizations in undertaking a terrorist attack are complex and not easily translated into a quantitative objective function.

What one would need to use in these models is not the actual consequences given a set of choices, which are potentially largely unknown to the adversary, but rather some measure of “perceived consequences” from the perspective of the terrorist – that is, what consequences they *think* they’ll get given a particular choice²⁴. Given the criticisms about data complexity of the BTRA in the NRC Report, the BDM implemented properly would require an *additional* (and non-existent) level of data about the adversary beyond what

²² NRC Committee. “DRAFT: A Call for Change” Page E-4.

²³ NRC Committee. “DRAFT: A Call for Change” Page D-6.

²⁴ Interesting, on page 7-2, the Committee asserts that the 2006 BTRA “probability assessment of terrorist decisions is independent of the potential consequences of the attack,” something that is not correct. While the BTRA does not optimize based on consequences as the Committee proposes, the intelligence analysts do in fact consider what the potential consequences may be given observed adversary choices. The Committee was made aware of this in DHS’ explanation of the probability elicitation process in August of 2006, as well as in the 2006 BTRA Report.

the BTRA requires. The BTRA has the admittedly difficult challenge of synthesizing the data and evidence of *actual terrorism intelligence data* as insight into their decision making. But the BDM would require DHS to somehow assess what the terrorists are *thinking* – what level of consequences they believe they’ll get – beyond the actions we already have a difficult time tracking and monitoring in intelligence. While DHS appreciates the recommendations to improve modeling the intelligent adversary, we must take into account the attainability of the input data. The NRC Report comments on this issue by stating on page 6 of the Executive Summary that “...determination of data sources and their reliability is outside the scope of this report.”²⁵

To complete the discussion of Recommendation #2, the Report’s ultimate conclusion in Recommendation #13, based in part on Recommendation #2, is curious in that the mechanisms used in the 2006 BTRA to elicit probabilities and consider the intent and decisions of terrorist adversaries were well known to the Committee from the material presented to them at the very first meeting in August 2006^{26,27}. The Committee illustrates its early awareness by extensively citing the need for improved “analysis of the intelligent adversary” in its Interim Report²⁸ (in fact, of the three Recommendations developed in the Interim Report, the one focused on intelligent adversary analysis gets the most attention). Given that the Committee cites “new information” in the final 2006 BTRA Report after the NRC Interim Report was complete as the justification for the movement away from their Interim Report findings of “adequate but incomplete”²⁹ and that the DHS “implementation... appears, for the most part, to be consistent with well-accepted practice in other fields of risk analysis...”³⁰, DHS does not comprehend how the contents of Recommendation #2 represent new information beyond what the Committee already knew when it issued the Interim Report with these findings. While DHS acknowledges the need to improve modeling the intelligent adversary, given the diverse scientific opinion within the risk analysis community, DHS does not understand the justification for the Report’s recommendations to discard the PRA analysis on these grounds.

NRC Committee Recommendation #4

*Normalization of BTRA risk assessment results obscures information that is essential for risk-informed decision making. BTRA results should not be normalized.*³¹

In the text surrounding this recommendation in the Executive Summary, there are two fundamental claims made by the NRC regarding normalization of risk in the 2006 BTRA

²⁵ NRC Committee. “DRAFT: A Call for Change” Page ES-6.

²⁶ Denning Richard S. PowerPoint Presentation “NAS_Review__08-28-06_Methodology--UNCLASS_v3.ppt” Presented to NRC Committee 28 August 2006, Slides 7-31.

²⁷ Carnell, RC *et al.* PowerPoint Presentation “NAS_Review__08-28-06_ConsequenceModels--UNCLASS_v2.ppt” Presented to NRC Committee 28 August 2006, Slides 4-16.

²⁸ NRC Committee. “Interim Report” Page 2, 9-11.

²⁹ NRC Committee. “Interim Report” Page 12.

³⁰ NRC Committee. “Interim Report” Page 1.

³¹ NRC Committee. “DRAFT: A Call for Change” Page ES-7.

– the assertion that DHS never explains how the normalization is done, and that normalization in fact *should not* be done in the first place. The Report states that “DHS has chosen to represent “normalized” relative risk, without specifying the normalization constant.”³² This assertion persists in the supporting sections of Chapter 3 as well, where the Committee states that the “normalization of 2006 BTRA results has irretrievably obscured the BTRA results...” and that “its essential details are absent from all underlying documentation.”³³ This is incorrect. In both the presentations to the Committee at its very first meeting in August 2006, as well as the 2006 BTRA Report, the normalization process is explained. The Committee did not agree with the approach, but it was communicated to them. First, the 2006 BTRA Report states that:

“Due to inherent uncertainties in bioterrorism risk analysis, risk is given as a dimensionless (unitless) quantity; the numbers in the y-axis scale are expressed relative to the total bioterrorism risk in the assessment, which is set to have a risk of 10^0 or 1. Specifically, all agent risks are expressed relative to the total mean bioterrorism risk.”³⁴

DHS believes this is a clear explanation of the normalization process. This same explanation – that each risk result was normalized to total bioterrorism risk – was provided to the NRC in the classified results briefing on 29 August 2006 as well.

Further evidence that the Committee understood the DHS normalization approach comes from an email exchange between Committee Member Stephen Pollock and DHS Statistical Support Staff Member, Dr. Nancy McMillan. In this exchange that occurred on 31 August 2006 (attached), a few days after the initial presentations to the Committee, Professor Pollock and Dr. McMillan discuss both the 2006 BTRA normalization approach, and an improved approach that Professor Pollock worked with Dr. McMillan to develop, which he refers to instead as ‘Relative Risk.’ Documentation provided by DHS to the NRC Committee, and communication with Committee members explained the normalization process. DHS does not understand this criticism in the NRC Report.

A more fundamental argument in Recommendation #4 however, is that normalization should not be done at all. This fact is subject to debate. The Committee’s statement in their Report that they wonder “how senior leadership has interpreted a normalized fatality scale (with no units) in the BTRA report and presentation materials”³⁵ was answered directly by the senior leadership on a number of occasions. Dr. James B. Petro, the Homeland Security Council (HSC) customer for the BTRA assessments spoke to the Committee at the 29 August 2006 meeting, indicating he was satisfied with the product and that relative agent prioritizations were useful to him and the HSC staff. Senior DHS leadership echoed this sentiment as well, with DHS S&T Under Secretary Jay M. Cohen clearly indicating directly to the Committee in his presentation (attached) on 8 February

³² NRC Committee. “DRAFT: A Call for Change” Page ES-7.

³³ NRC Committee. “DRAFT: A Call for Change” Page 3-22.

³⁴ Bioterrorism Risk Assessment. 2006. Department of Homeland Security, Pages 2-2, 2-3.

³⁵ NRC Committee. “DRAFT: A Call for Change” Page 3-22.

2007 that both the White House HSC and DHS components were interested in relative risk, not absolute risk.³⁶

The fact that the Committee argues against normalization in the NRC Final Report is somewhat inconsistent given the email exchange (attached) described above between Dr. McMillan and Professor Pollock. In it, Professor Pollock assists DHS staff in developing an *improved* normalization/relative risk approach for use in the 2008 BTRA, which in fact was implemented. DHS was surprised to learn the Committee's position in the Final Report given the level of effort from Dr. Pollock in helping DHS develop the improved relative risk methodology, which has been implemented successfully in the 2008 BTRA. This methodology, while slightly different from the normalization approach used in 2006, has the same effect the Committee criticizes – that the magnitudes of the risk are obscured by a dimensionless, relative risk.

DHS believes it provided a clear explanation of how the normalization was done and of how senior leadership interprets and uses normalized, dimensionless risk results. DHS does not believe Recommendation #4 provides sufficient reason to discard the 2006 BTRA analysis as a whole. Removing the normalization is a “push of a button” modification (as simple as choosing to not divide the risk results by the total risk when presenting results in figures), and is not a critical methodological flaw. Finally, as obviated by the attached email exchange between Professor Pollock and Dr. McMillan, the Committee has demonstrated that they were aware of the normalization approach within days of the first meeting in August 2006 – months before the delivery of the Interim Report. It should be noted that this issue was not mentioned as a critical flaw in the Interim Report. The Committee claims that their departure from assessing the 2006 BTRA to be “adequate but incomplete” in the Interim Report to “should not be used” in the Final Report is justified by having been allowed to review the 2006 BTRA Report after the Interim Report was delivered. As noted above, this normalization issue was clear from discussions and email communication following the initial meeting, and was described in the 2006 BTRA Report. While DHS acknowledges that there is debate on the “value” of normalization, DHS does not believe Recommendation #4 supports Recommendation #13's conclusion that the BTRA “should not be used...for decision making.”

NRC Committee Recommendation #10

*Recommendation 10: The Susceptible, Exposed, Infected, and Recovered (SEIR) model adopted by DHS is more complex than can be supported by existing data or knowledge. DHS should make its SEIR model as simple as possible consistent with existing knowledge.*³⁷

³⁶ Cohen, Jay M. PowerPoint Presentation “NAS 2-8-07_Vitko.ppt” Presented to NRC Committee 8 February 2007, Slide 9.

³⁷ NRC Committee. “DRAFT: A Call for Change” Page ES-10

There are numerous questions surrounding the material presented in Chapter 6 that is intended to support Recommendation #10. There are only three-and-a-half pages of analysis presented prior to the recommendation text as support (to include a full page, single footnote). There is almost no material presented in this section that supports the recommendation as specifically applicable to the 2006 BTRA. In a review chapter on this topic, one might expect an analysis of the infectious disease agent input data used in the 2006 BTRA medical mitigation model, or possibly an analysis of the literature surrounding infectious disease parameters to show where the BTRA was accurate, where it was not accurate, etc. This is not presented, rather a generalized discussion of the difficulties of SEIR modeling is presented, accompanied by several examples of recent epidemiological modeling efforts. The reader reaches Recommendation #10 on page 6-5, without being presented with any arguments or examples specific to the analysis under review – the 2006 BTRA – on the previous five pages in the chapter. It should be noted that a concise and clear table highlighting all infectious disease input parameters in the 2006 BTRA is presented in Appendix A of the 2006 BTRA Report. These infectious disease agent parameters were drawn from over 2800 literature articles, and were vetted by public health experts around the Government, such as CDC, NIH, DoD, and others. There is no mention of this information in the NRC Report.

In addition, what Chapter 6 omits is as concerning as what it includes. Despite the title's reference to "Improving Bioterrorism Consequence Assessment," the vast majority of the consequence modeling executed for the BTRA assessment is mentioned nowhere in Chapter 6, nor anywhere else in the Report, save a few sentences in Chapter 3. DHS conducted extensive, physically-based food and water contamination modeling, single-zone indoor aerosol modeling, outdoor aerosol modeling to include meteorological variability, building protection factors, and other attributes, and a host of other analyses as part of the consequence modeling. These analyses are critical aspects of the consequence modeling (and therefore risk) analyses conducted by DHS. It was anticipated that NRC would review this material as part of its charge, yet little if any mention is made of them. The consequence models were presented to the committee as part of an 87-slide PowerPoint presentation on 28 August 2006 entitled "NAS_Review__08-28-06__ConsequenceModels—UNCLASS_v2.ppt," which is an attachment to this document. Further, the consequence modeling is expanded in mathematical detail in Section 5.6 and Electronic Appendix E2³⁸ of the 2006 BTRA Report. It is not clear why these models were not reviewed as part of the Committee's efforts. There is scant mention of these in the NRC Final Report when there are almost 1800 pages of Electronic Appendices associated with the Full BTRA Report.

The focus of Chapter 6 is on the medical mitigation model; however, it is evident that the Committee has reviewed the **wrong model**. On 9 February 2007, DHS was asked by the Committee to present updates on model improvement activities for the anticipated 2008

³⁸ Electronic Appendix E2 is part of a larger set of BTRA Report appendices too expansive to provide in printed form. These 1800 pages of supporting appendices were provided on CD-ROM to the NRC Committee with the printed BTRA Report sections. DHS sees no indication from the contents of the NRC Final Report that this important material was ever considered as part of the NRC's review. Electronic Appendix E2 is distinct from Appendix E in the printed 2006 BTRA Final Report.

BTRA. As such, an attached 31-slide presentation entitled “NAS 020907 draft DHS – mg CAD tfh SPB.ppt” was presented in which potential medical mitigation modeling approaches based on SEIR were being considered for 2008. The material presented in this briefing was not the 2006 BTRA medical mitigation model. The actual 2006 BTRA model was presented to the Committee at its initial meeting on 29 August 2006³⁹ and is explained in Section 5.7 and Appendix C2 in the 2006 BTRA Report. Recommendation #10 and Chapter 6 focus only on SEIR modeling – while this was proposed as an underpinning for all agent analysis in the 2008 BTRA, the 2006 BTRA used SEIR modeling for only the 6 contagious agents out of the 28 agents assessed. Despite the sweeping nature of Recommendation #10, and how it is used to support Recommendation #13, no mention is made of the actual medical mitigation model developed and employed to generate morbidity and mortality values for the remaining 22 agents, which include some of the most important bioterrorism agents such as *B. anthracis* and *C. botulinum* toxin, and *F. tularensis*.

DHS believes that the Committee has reviewed the incorrect model because an invited guest to the 9 February 2007 presentation (the presentation focused on potential 2008 enhancements) sent an email with his impressions of that presentation to the NRC staff officer for the NRC review (Dr. Neal Glassman). Portions of this email correspondence are used *uncited* in Chapter 6 (this email was forwarded to the DHS BTRA Program Manager, Dr. Steve Bennett by Dr. Glassman). Specifically, Professor Marc Lipsitch attended only a fraction of this presentation, and wrote the following as part of his email to Dr. Glassman (attached to this document):

“Soon after 9/11/2001, several of the world’s most prominent infectious disease modelers undertook studies of the likely magnitude of smallpox epidemics under various response scenarios. Despite the availability of excellent data from smallpox epidemics in recent years, there was considerable disagreement about the likely adequacy of various responses (particularly targeted/traced vaccination). It took several years, multiple articles, letters, discussions, and other interactions to clarify that the crux of disagreement was about the timing of transmission relative to symptoms and to the likely speed of public health response.”⁴⁰

On page 6-4 of the NRC Report, almost identical text appears:

“Soon after the 9/11 terrorist attacks, several prominent infectious disease modelers undertook studies to assess the likely magnitude of smallpox epidemics under various response strategies... Despite available quantitative data from past smallpox epidemics, there was considerable disagreement about the likely adequacy of various responses. It took several years and considerable debate to understand that the differences in models’ conclusions rested mainly upon

³⁹ Carnell, et al. PowerPoint Presentation “NAS_Review__08-28-06__ConsequenceModels—UNCLASS_v2.ppt” Presented to NRC Committee, 29 August 2006. Slides 65-75.

⁴⁰ E-mail correspondence between Professor Marc Lipsitch, Harvard University, and Dr. Neal Glassman, NRC staff officer; provided to Dr. Steve Bennett by Dr. Glassman 26 February 2007.

assumptions about the timing of transmission relative to symptoms, and about the likely speed of the public health response.”⁴¹

The above text, although uncited and not properly attributed to Professor Lipsitch, only relates to some supporting general points about epidemiological modeling and the importance of data assumptions. More troubling is the following material, also uncited, that *forms the core of the Committee’s actual recommendation* as stated immediately following Recommendation #10 on Page 6-5. Again, Professor Lipsitch writes in his email to Dr. Glassman:

“The complexity of the model is too great for the data and resources available...I emphasize that the use of a complex model when adequate data are unavailable is not just inappropriate, but is likely strongly detrimental to the quality of conclusions. It will be impossible to elicit sensible estimates, uncertainty ranges, and correlations in the uncertainty for all of these parameters from subject matter experts. Hence the uncertainty coming out of the model will likely be misspecified. Furthermore, the complexity of the model makes it extremely difficult to use intuition or simpler models to check its outputs...”⁴²

And again, nearly identical and *uncited* text appears in the Committee Report, page 6-5, as the core text supporting Recommendation #10:

“The complexity of the consequence models presented by DHS seems too great given the data available. Use of a complex model when adequate data are unavailable is probably detrimental to the quality of conclusions; and it may be dangerously misleading. It compromises the ability to elicit sensible estimates, uncertainty ranges, and correlations in the uncertainty for all of the parameters obtained from subject matter experts. Hence the uncertainty of the model will likely be incorrectly estimated. In addition, complex models don’t lend themselves will to independent validation and verification by others.”⁴³

By his own admission elsewhere in his email, Professor Lipsitch arrived late, hearing only “most of the presentation”⁴⁴ on 9 February 2007, and further qualifies his email indicating that he “had only an hour’s exposure to the work.” It is ironic that in his email to DHS BTRA Program Manager Dr. Steve Bennett containing Professor Lipsitch’s comments, Dr. Glassman writes that “they are his comments and not those of the Committee”⁴⁵ – yet it appears to DHS that Professor Lipsitch’s comments did get incorporated into the NRC Final Report (uncited).

⁴¹ NRC Committee. “DRAFT: A Call for Change” Page 6-4.

⁴² E-mail correspondence between Professor Marc Lipsitch, Harvard University, and Dr. Neal Glassman, NRC staff officer; provided to Dr. Steve Bennett by Dr. Glassman 26 February 2007.

⁴³ NRC Committee. “DRAFT: A Call for Change” Page 6-5.

⁴⁴ E-mail correspondence between Professor Marc Lipsitch, Harvard University, and Dr. Neal Glassman, NRC staff officer; provided to Dr. Steve Bennett by Dr. Glassman 26 February 2007.

⁴⁵ E-mail correspondence between Dr. Neal Glassman, NRC staff officer, and Dr. Steve Bennett, DHS BTRA Program Manager. 26 February 2007.

While his late arrival to the presentation probably explains why Professor Lipsitch did not realize that he was seeing proposed changes for the 2008 BTRA, and not a presentation of the 2006 BTRA medical mitigation model, it appears to DHS that the NRC used this individual as a primary source of its review, resulting in a review of the wrong model. Professor Lipsitch did not attend any of the other meetings or briefings where the proper medical mitigation model was presented in August 2006, nor did he attend any of the results briefings or review the 2006 BTRA Report in any way. Rather, he attended *part* of a 2008 BTRA planning briefing, and sent a short email to Dr. Glassman about his impressions. DHS believes information from a non-Committee member should not be featured so prominently in key recommendations. It should be noted that this material is not properly referenced and attributed, appearing as though it is original work written by the author(s) of Chapter 6.

Given that the incorrect medical mitigation model for the 2006 BTRA was reviewed in the NRC Final Report, DHS does not believe Recommendation #10 and its supporting content in Chapter 6 are valid. This chapter represents an incorrect conception of 2006 BTRA consequence modeling, and DHS does not find this recommendation valid in supporting Recommendation #13. The proper medical mitigation model was briefed at the very first meeting in August 2006, well in advance of the Interim Report, which makes no mention of these issues.

NRC Committee Recommendation #11

*Recommendation 11: While human mortality and the magnitude and duration of morbidity should remain the primary focus of DHS bioterrorism risk analysis, DHS should incorporate other measures of societal loss including the magnitude and duration of first- and second-order economic loss, environmental, and agricultural effects.*⁴⁶

As requested by DHS in its charge to the Committee⁴⁷, the Committee provides a thoughtful, concise, and useful discussion of approaches for combining morbidity and mortality consequence measures in pages 6-5 to 6-8 of their Final Report, as well as recommendations on how to incorporate relevant economic consequence analyses into the assessment framework – ideas that DHS looks forward to implementing in upcoming BTRA assessment cycles. That said, DHS does not see the basis for this recommendation as a justification for the departure from the Interim Report recommendations of “adequate but incomplete” to those of the Final Report: “BTRA...should not be used.”

In Chapter 1, the Committee refers to its post-Interim Report review of the 2006 BTRA Report as the key reason for the change in conclusions between the NRC’s Interim and Final Reports. This cannot be the case for Recommendation #11, because the Committee

⁴⁶ NRC Committee. “DRAFT: A Call for Change” Pages ES-10, 6-7.

⁴⁷ NRC Committee. “DRAFT: A Call for Change” Page ES-3, Committee charge item #2 – “Recommend further improvements to the consequence analysis component of the methodology, including its models of economic effects.”

gives significant attention to this issue in the Interim Report. Specifically, the Committee writes that:

“Currently, the PRA computes measures of mortality, morbidity, and direct economic costs...But indirect economic costs...must also be included. DHS is planning to use input-output models and CREATE-developed general equilibrium models to improve its estimates of the direct economic consequences of terrorist events in its FY08 risk assessment. Both of these techniques can be used to estimate the indirect costs. The committee agrees that their use is appropriate for the next stage of model development.”⁴⁸

The Committee not only understood the consequence metrics in the 2006 BTRA, but also acknowledged S&T’s plans to extend them, and agreed with both the partners and approaches selected for the 2008 BTRA. It is unclear what new information in the 2006 BTRA Report provided information about the scope of the consequence metrics beyond what was already known and stated by the Committee in the Interim Report.

Further, as part of the 2008 BTRA, DHS S&T has now designed, executed, and completed the consequence extensions (including indirect economic effects, environmental effects, and agricultural impacts) requested by Recommendation #11 the Final Report and approved by the committee in the Interim Report as part of the 2008 BTRA, and the Committee was kept abreast of progress in these efforts throughout 2007^{49,50}. Additional consequence recommendations in Chapter 6 of the NRC Report regarding social disruption and behavioral impacts are also included in the 2008 BTRA as part of the indirect and induced economic modeling efforts, as the Committee was aware⁵¹. A full treatment of social and psychological impacts is theoretically possible, and DHS is in fact exploring this, but the Committee does not solve the quantification difficulties associated with doing this, citing references that indicate “long term social and psychological effects of biological attack *may* be as damaging as the acute ones; that they *may* remain high for years; and that they *may* exacerbate pre-existing psychiatric disorders and further heighten the risk of mass sociologic illness...”⁵² (emphasis ours). The disability-adjusted life-year (DALY) and quality-adjusted life-year (QALY) advocated for use by the Committee⁵³ must have parameters that are quantified for how much impact bioterrorism would have on social and psychological health. This has never been done to our knowledge, and no reference for this information is cited by the Committee. DHS agrees that these are important areas for future research; however, the fact that these are missing from the 2006 BTRA does not mean that the 2006 BTRA

⁴⁸ NRC Committee. “Interim Report” Page 10.

⁴⁹ Bennett, SP. PowerPoint Presentation “ResponseToInterimReport_02-10-07.ppt”. Presented to NRC Committee 10 February 2007.

⁵⁰ Gisi, M and Dingus, C. PowerPoint Presentation “NAS 020907 draft DHS- mg CAD tfh SPB.ppt”. Presented to NRC Committee 9 February 2007.

⁵¹ Hale, T. PowerPoint Presentation “NAS_Review_08-29-06_2008improvement—UNCLASS_v2.ppt”, slides 39-44. Presented to NRC Committee 29 August 2006.

⁵² NRC Committee. “DRAFT: A Call for Change” Page 6-6.

⁵³ NRC Committee. “DRAFT: A Call for Change” Page 6-6.

analysis is not valuable in its reporting of risk for other consequence metrics such as mortality, morbidity, and economic impact.

For these reasons, DHS does not see how Recommendation #11 supports the conclusion that the 2006 BTRA should not be used as a basis for decision making, and finds it inappropriate for the Committee to claim in the NRC Final Report that issues of scope, as opposed to technical quality of methodological execution, are the basis for rejection of an important analysis, given that the Committee reports no sources of additional information regarding this issue beyond what it demonstrably knew and reported in the Interim Report. At best, DHS has already satisfied this issue in the 2008 BTRA, a fact of which the Committee is aware, and with an approach and executing team approved by the Committee; at worst, this criticism is an issue of scope, not methodology. DHS does not believe that this scope-related issue serves as supporting evidence for Recommendation #13.

“Mathematical and Statistical Errors”

Recommendation #13, which advocates that the 2006 BTRA should not be used for decision making, is based on two arguments in the Executive Summary. The first is “For the reasons noted in Recommendations 2, 4, 10, and 11”⁵⁴. The Committee also supports Recommendation #13 based on “mathematical errors, risk assessment modeling mistakes, shortcomings in presentation, and other weaknesses in BTRA 2006”⁵⁵ that include “unnecessary complexities.” These are extremely broad and fundamental statements, echoed throughout the Executive Summary⁵⁶ – statements that if true, certainly are convincing reasons for DHS to discard the 2006 BTRA, at least until these errors are corrected or addressed. As shown below however, DHS believes these broad claims about the 2006 BTRA analysis are not founded.

Despite extensive technical review of the NRC’s Report, DHS can find only **three** instances in the Committee’s description of the 2006 BTRA that might rise to the level of actual mathematical errors. These are summarized here, and in detail in the attached document, “AllegedMathematicalErrors_v5.doc.”

The first of these appears in Chapter 3 in a discussion on pages 3-13 and 3-14 regarding the nature of the probability distributions used in the 2006 BTRA event tree. Specifically, the committee claims that the 2006 BTRA methodology samples probabilities for multi-way splits incorrectly because it samples marginal probabilities for each branch according to a beta distribution, leading to a set of multi-way split probabilities that do not sum to 1, and that the probabilities should have a joint distribution that captures the dependencies, the most important being that the probabilities sum to 1. The NRC Report claims that “Each of these outcome selection probability solicitations is converted into a

⁵⁴ NRC Committee. “DRAFT: A Call for Change” Page ES-11.

⁵⁵ NRC Committee. “DRAFT: A Call for Change” Page ES-4.

⁵⁶ NRC Committee. “DRAFT: A Call for Change” Page ES-2, ES-4, ES-4, elsewhere.

marginal probability density of probabilities for selecting the particular outcome”⁵⁷ and argue instead that “the outcome probabilities should have a *joint* distribution that captures their dependencies (the most important being that they sum to 1).”⁵⁸ (emphasis theirs).

In reality, the 2006 BTRA has no sampling of marginal beta distributions whatsoever, and the approach outlined in the 2006 BTRA report in fact does guarantee that the outcome probabilities have a joint distribution that sum to 1. This fact is clear in the BTRA Report – the process for drawing frequencies for multi-way splits is outlined and explained in detail in Appendices C and D (particularly, Figures C-4, D-3, and D-4). Relevant excised material from these appendices is attached to this document in “AllegedMathematicalErrors_v5.doc” In addition to the description in the BTRA Report, these issues were raised by the Committee Chair, Professor Greg Parnell, and a key member of the Committee, Professor Gerald Brown, in spring of 2007. Several conference calls were convened, during which discussions between DHS and Professors Parnell and Brown occurred, and a document explaining how the 2006 BTRA worked in this area (drawing largely from the aforementioned 2006 BTRA Appendices) was provided. During the conference calls and exchange of information, Professors Parnell and Brown concurred that DHS’ explanation was clear, and did not indicate that they still had questions about the nature of the probabilities assigned to the multi-way splits in the event tree. DHS does not know why this misunderstanding still exists in the Final Report, given the description in the 2006 BTRA Report, and the clarifying explanations to the Committee during the Spring 2007 conference calls.

The second alleged mathematical error also is in Chapter 3, relating to the manner in which the 2006 BTRA models multiple bioterrorism attacks. The Committee rightly identifies a typographical error in an equation in the 2006 BTRA Report characterizing the expected number of attacks prior to interdiction⁵⁹. Further, an attempt to clarify this mistake was also problematic as the Committee points out⁶⁰. While this does in fact represent the only actual mathematical error DHS can identify in the NRC Report, DHS explained to Professors Parnell and Brown in the spring of 2007 that since the “multiple attacks” model was a modifier of the frequency of attack initiation, this error *has no impact on risk as presented in the 2006 BTRA* since the results are presented normalized against total bioterrorism risk^{61,62}. Were the 2006 BTRA to report absolute risk, this error may have introduced an effect, but even under that case, DHS demonstrated to the Professors Parnell and Brown that the effect of the error impacted risk by a factor of ½, not an order of magnitude as claimed in the NRC Report⁶³. The attached document, “DHSresponseTwoFindings_v1.doc” which was sent to Parnell and Brown on 14 May 2007, responds to text written by the Committee that asserts two findings as they

⁵⁷ NRC Committee. “DRAFT: A Call for Change” Page 3-13.

⁵⁸ NRC Committee. “DRAFT: A Call for Change” Page 3-14.

⁵⁹ NRC Committee. “DRAFT: A Call for Change” Page 3-17.

⁶⁰ NRC Committee. “DRAFT: A Call for Change” Page 3-18.

⁶¹ Attached Document, “DHSresponseTwoFindings_v1.doc” Pages 2-4. Provided to the Committee Chair, 14 May 2007.

⁶² Attached Document, “AllegedMathematicalErrors_v5.doc” Pages 2-4. Provided to the Committee Chair, 14 May 2007.

⁶³ NRC Committee. “DRAFT: A Call for Change” Page 3-18.

understood them at that time. The text in finding #2 of this document, “Estimating number of multiple attacks” is almost identical to what now appears in the Final Report. Despite DHS’ response in this document, no mention is made in the NRC Report that this finding was reconciled with Professors Parnell and Brown or that DHS showed that there was no risk impact to this error. DHS does not know whether or not the extensive technical exchange that occurred with Professors Parnell and Brown was shared with the remainder of the Committee. Based on both personal communications during the conference calls and a series of technical documents explaining the impacts of the error, such as the attached document mentioned above, the NRC final reports omits the fact that all risk results (and derived conclusions) as presented in the 2006 BTRA are unaffected by the multiple attack error. To summarize, this “error,” does not have any impact on the 2006 BTRA whatsoever, because the customers of the report required normalization of the risk results. While DHS thanks the Committee for identifying the error so that it can be corrected, DHS does not believe this should be counted as one of the “many mathematical errors” that “corrupt results” described in the Executive Summary as justifying the recommendation that the 2006 BTRA should be discarded.

The final potential error to which the Committee could be referring relates to the design and execution of the Latin Hypercube Sampling (LHS) approach used to sample from the probability distributions in the 2006 BTRA event tree. First, the Committee claims “Documentation presented to this committee contains no detail of the sample design...”⁶⁴ However, on page C3-84 of the 2006 BTRA, the method of constructing the Latin Hypercube Sample is referenced from Stein (1987). Specifically, Page 144 of Stein states:

“I now describe the procedure for producing a Latin hypercube sample of size N as given by McKay et al. (1979). Define $P = (p_{jk})$ to be an $N \times K$ matrix, where each column of P is an independent random permutation of $\{1, 2, \dots, N\}$. Moreover, let ξ_{jk} ($j = 1, \dots, N; k = 1, \dots, K$) be NK iid $U[0, 1]$ (uniformly distributed on $[0, 1]$) random variables independent of P . Then X_{jk} is defined by $X_{jk} = F_k^{-1}(N^{-1}(p_{jk} - 1 + \xi_{jk}))$.”⁶⁵

Also in Appendix C3 (page C3-81,82, Figures C-3 and C-4), the methodology appendix to the 2006 BTRA Report, the process for determining the distribution functions (F_k) for the independent random variables (X_k) was described. Note that this section recognizes that sampling multi-way split distributions requires dependent random variables and describes the process by which the multi-way splits were reduced to a series of binary splits such that the Latin Hypercube Sample considered one independent random variable (X_k) from each binary split. This same discussion occurred over the conference calls described earlier in this discussion – consequently, DHS does not agree with the Committee’s claim that the sample design was not documented.

⁶⁴ NRC Committee. “DRAFT: A Call for Change” Page 3-14.

⁶⁵ Stein M. Large Sample Properties of Simulations Using Latin Hypercube Sampling. *Technometrics* 1987;29(2):143-151.

Regarding LHS, the Committee’s consultant, Professor Alan Washburn echoes statements similar to those made by the Committee in Chapter 3. Specifically, Professor Washburn states in Appendix I:

“DHS claims graphically that the LHS sample fractiles are also the fractiles of the random variable $E(Y_a|\theta)$. I suspect that this claim is false. LHS sampling is basically a variance reduction technique that makes the variance of Y_a smaller than it would be with ordinary sampling.”⁶⁶

The committee claims in Chapter 3 that “... this sampling design produces unbiased estimates of the mean and quantiles *with asymptotic sample size*. Further, see Stein (1987), page 144 Equation (3) and section 5, ...”⁶⁷ DHS is puzzled by Professor Washburn’s and the Committee’s claims that LHS quantiles are not unbiased and that asymptotics are required to produce unbiasedness. This is not true as Stein, the reference cited by the Committee itself, clearly states: “If Latin Hypercube Sampling as described in Section 2 is used, then $\tilde{h}(X)$ is still unbiased.”⁶⁸ The function $\tilde{h}(X)$ can be defined to be the identity function, in which case the mean is shown to be unbiased, or the usual estimator of the empirical distribution function, in which case the quantiles are shown to be unbiased⁶⁹. Latin Hypercube Sampling as described in Stein, Section 2 is exactly the procedure the 2006 BTRA referenced and used to produce unbiased estimates.

One possible explanation of the Committee’s confusion comes from their reference to Stein, section 5, as a relevant citation. However, this section refers to methods for constructing Latin Hypercube Samples for *dependent* random variables – this procedure was not used in any manner in the BTRA, as the sampling of dependent random variables was not required due to the process, described on page C3-81,82, by which the multi-way splits were reduced to a series of binary splits such that the Latin Hypercube Sample considered variables (X_k) from each binary split.

The committee’s last comment on LHS was “Moreover, the variance may be decreased or *increased* by this design, depending on the covariance structure of the distributions sampled.” Because the functions of the Latin Hypercube Sample calculated in the 2006 BTRA, risk, are not monotonic, DHS agrees that this is possible. However, Stein states “I will show, however, that as $N \rightarrow \infty$, the covariance term is asymptotically non-positive.”⁷⁰ Therefore, while the 2006 BTRA Report does not document that the sample size chosen was sufficient to produce a non-positive covariance term, which would have ensured that LHS was more efficient than simple Monte Carlo sampling, this concern does not cast doubt on the 2006 BTRA results; it only indicates that there may have been

⁶⁶ NRC Committee. “DRAFT: A Call for Change” Page I-4.

⁶⁷ NRC Committee. “DRAFT: A Call for Change” Page 3-14.

⁶⁸ Stein M. Large Sample Properties of Simulations Using Latin Hypercube Sampling. *Technometrics* 1987;29(2):143-151.

⁶⁹ McKay M.D., Beckman R.D., and Conover W.J. A Comparison of Three Methods for Selecting Values of Input Variables in the Analysis of Output from a Computer Code. *Technometrics* 1979:21(2):239-245. Page 242.

⁷⁰ Stein M. Large Sample Properties of Simulations Using Latin Hypercube Sampling. *Technometrics* 1987;29(2):143-151.

a sampling approach which would have produced risk estimates with less variability. DHS does not believe this is a sufficient reason to discard of the entire 2006 BTRA analysis.

To summarize, DHS has been able to find scant evidence of the mathematical errors and corrupted results the Committee references in its sweeping statements in the Executive Summary. There are other issues raised by the Committee related to normalization, and the complexity of the probability elicitation, but these are not mathematical *errors* (they are however, dealt with elsewhere in this document). The only possible errors DHS could find in the Final Report are trivial and/or not accurate, and as such we believe do not warrant discarding the entire BTRA analysis. It should be noted that the supposed errors in the analysis were first identified and communicated to DHS by Professor Alan Washburn, author of Appendix I in the NRC Report, a non-Committee member and third-party reviewer who did not attend NRC Committee meetings, did not receive the DHS briefings, and did not participate in any of the spring 2007 conference calls during which these issues were discussed and addressed.

DHS does not believe the Committee has supported its claims in the Executive Summary with respect to the assertions of extensive mathematical errors and corrupted results; DHS would welcome clear identification of such errors in the NRC Report. The peer-review process employed by the Academies, while an essential part of the scientific process in any methodology review such as this one, would have been unable to identify many of the Report inaccuracies or mischaracterizations. DHS is confident that peer reviewers reviewed all of the material provided them by the NRC, but since the peer reviewers could not review the 2006 BTRA report itself (a classified document) nor were they likely provided with DHS' responses to the Committee on these issues in the spring of 2007, reviewers could only see the *Committee's* description of the 2006 BTRA, which DHS argues is inaccurate.

In addition to the alleged “mathematical errors” in the document, the Committee refers to “unnecessary complexities” as well. The largest of these appear to be the elicitation of probability distributions in the 2006 BTRA, as opposed to just fixed-value probabilities. The Committee writes in Recommendation #3 that “the event tree probability elicitation should be simplified by assessing probabilities instead of probability distributions for the outcomes of each event,”⁷¹ and that assessing distributions of probabilities is “shown to be unnecessary; the analysis is unchanged if only the expected value of these distributions is used.”⁷²

The reason the 2006 BTRA elicits distributions instead of expected values is to represent the large degree of uncertainty associated with these probabilities. The Committee itself recognizes the need to incorporate and describe uncertainties elsewhere in the document indicating in Chapter 1 that “Risk analysis needs to address bioterrorism uncertainties”⁷³ and in Chapter 4 that there is high uncertainty in terrorism probabilities, a fact that must

⁷¹ NRC Committee. “DRAFT: A Call for Change” Page ES-7.

⁷² NRC Committee. “DRAFT: A Call for Change” Page ES-6.

⁷³ NRC Committee. “DRAFT: A Call for Change” Page 1-10.

be clearly communicated to decision makers.⁷⁴ Consequently, it is difficult to understand how the Committee advocates in Recommendation #3 that DHS ignore all epistemic uncertainty in the probability estimates in favor of expected values, while at the same time (rightly) indicating that uncertainty is critical in the representation of results to consumers of the analysis. Had DHS ignored epistemic uncertainties in its 2006 BTRA as the Committee seems to suggest, decision makers would have accepted a “1 to N” ordinal risk ranking of bioterrorism agents as sound, which is not at all the case when the uncertainties are communicated. While the Committee seems to think that the probability distributions are unnecessarily complex, DHS believes that what they provide – an indication of uncertainty in the estimates – is invaluable to the leadership. DHS does not understand Recommendation #3 in light of the other sections of the report highlighting the importance of uncertainty.

Examining the details of the Committee’s proposed alternatives to eliciting and sampling probability distributions may prove useful in understanding the Committee’s recommendations in this area. In Chapter 2, Dr. Alyson Wilson and Professor Pollock write that without sampling from the distributions, (1) “this represents a significant computational simplification”⁷⁵ and (2) “What is lost...is the family of risk curves. However *no analysis in 2006 BTRA...use the additional information in the family of risk curves.*”⁷⁶ (italics as written in the NRC Report). Regarding (1), it is technically true that the tree and the associated computation would get simpler. But that is by no means a significant simplification in terms of computation time – solving the entire PRA tree as it currently is implemented takes only minutes⁷⁷. Most of the calculation time in the 2006 BTRA is in the consequence analyses, which are for the most part, not reviewed or mentioned in the NRC Report⁷⁸

The NRC Final report does not accurately convey the use of the family of risk curves. The risk curves form the foundation of the first key finding of the 2006 BTRA, and associated analysis occurs throughout the 2006 BTRA Report. Specifically, the very first figure in the results chapter of the 2006 BTRA is a family of risk curves (CCDFs) used to draw several striking conclusions about bioterrorism risk.⁷⁹ Further, Appendix A of the 2006 BTRA provides 83 pages of detailed agent analyses that include, and are based upon, the risk curves derived from the analysis. Moreover, these risk curves provide the sole mechanism for visualizing the uncertainties in the agent point estimates of risk, since these estimates are derived directly from the risk curves. This is a significant misunderstanding of the 2006 BTRA results and analyses.

Summary

⁷⁴ NRC Committee. “DRAFT: A Call for Change” Page 4-11.

⁷⁵ NRC Committee. “DRAFT: A Call for Change” Page C-8.

⁷⁶ NRC Committee. “DRAFT: A Call for Change” Page C-8.

⁷⁷ Carnell, et al. PowerPoint Presentation “NAS_Review__08-28-06__ConsequenceModels—UNCLASS_v2.ppt” Presented to NRC Committee, 29 August 2006. Slide 87.

⁷⁸ Chapter 6 provides a cursory review of SEIR modeling, just a small fraction of the consequence analyses performed in the 2006 BTRA.

⁷⁹ Bioterrorism Risk Assessment. 2006. Department of Homeland Security, Page 2-1.

To summarize, DHS does not believe that the Committee has supported many of its key recommendations as laid out in the Final Report, nor has it adequately justified its departure from the Interim Report finding that the 2006 BTRA, while in need of improvement, was in fact adequate. In the material discussed above, DHS has highlighted that the four key recommendations upon which the overall conclusions are based, are based on inaccurate information about the 2006 BTRA analysis, or are overreaching in their statements about the appropriateness of probabilistic techniques in terrorism risk analysis.

Further, the NRC Final Report has not demonstrated any significant mathematical or statistical errors in the 2006 BTRA, as strongly asserted in the Executive Summary. Rather, the charged errors are largely misunderstandings of the analysis, or were shown to have no impact on risk results as presented.

The NRC Final Report omits descriptions of large components of the analysis, such as the thousands of pages of consequence analyses, and the entire Multi-Attribute Risk Analysis model, which served as a parallel approach to PRA, confirmed much of its results, yet was mentioned in only three sentences of the NRC Report.

In closing, DHS felt compelled to highlight the factual and scientific inaccuracies observed during its security review, and is willing to work with the Academies and the NRC to ensure that an accurate report is published as quickly as possible.