

ABSTRACT

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 STAKEHOLDER ENGAGEMENT
 PROCESSES: A CASE STUDY

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Risk engineers conduct comprehensive risk assessments for many types of large projects, often singularly focused on the technical assessment and its value to the technical engineering team. Limiting or excluding community stakeholder involvement from the assessment process increases stakeholder skepticism, apprehension, and mistrust regarding safety, health and welfare of those stakeholders living or working nearby. Social experts have repeatedly documented connections between perception framing, communication processes, and risks. This research considers the connections between stakeholder perceptions and communication plans associated with risks listed in the risk register, and communication plans designed based upon including social expert suggestions for six projects: three biosafety laboratories; two levee system assessment projects; and one Superfund site. The project risk assessment value is researched through the lens of risk perception and

communication planning via the risk register. The concept of a Risk Perception Management (RPM) Plan developed in collaboration with social science experts and integrated with the risk register is presented. This research shows how the RPM concept iteratively captures stakeholder perceptions to build associated communication plans, thus increasing risk assessment value for stakeholders and decision-makers.

RISK ASSESSMENT STAKEHOLDER ENGAGEMENT PROCESS MANAGEMENT:
A CASE STUDY

By

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Dedication

This project is dedicated to my family, who unwaveringly welcomed and supported the opportunity to pursue this effort.

“Not everything that can be counted counts,

and

Not everything that counts can be counted.”

- Albert Einstein

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I acknowledge and thank Dr. Greg Baecher for assistance, guidance and direction on this research project. I am grateful for his willing advice and shepherding my progression through this process.

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List of Abbreviations

AB 1200 Assembly Bill 1200
APL Johns Hopkins University Applied Physics Lab
BDCP Bay Delta Conservation Plan
BKC Biodefense Knowledge Center
BSL-3 Biosafety Level 3
BSL-4 Biosafety Level 4
BRA Boston Redevelopment Authority
BRP Blue Ribbon Panel
BU Boston University
CALFED California Bay-Delta Authority
CDA Coeur d' Alene
CDC Center for Disease Control
CLC Community Liaison Committee
DHS Department of Homeland Security
DRMS Delta Risk Management Strategy
DSRASSA Draft Supplementary Risk Assessment and Site Suitability Analysis
DWR Department of Water Resources
ERP Ecosystem Restoration Program
EIS Environmental Impact Statement
FEIS Final Environmental Impact Statement
EPA Environmental Protection Agency
FMDv Foot-and-mouth disease virus
GAO General Accounting Office
GIS Geographic Information Systems
HBAC Heartland BioAgro Consortium
HPAC Hazard Prediction Assessment Capability
HSDRRS Hurricane and Storm Damage Risk Reduction System
HSPD-9 Homeland Security Presidential Directive 9
IPET Interagency Performance Task Force
IRP Independent Review Panel
LAI Laboratory-Acquired Infection
LLNL Lawrence Livermore National Laboratory
MCMT&E Medical Countermeasures Test & Evaluation Facility
MEPA Massachusetts Environmental Protection Agency
MIT Massachusetts Institute of Technology
MWD Southern California Metropolitan Water District
NBAF National Bio- and Agro-Defense Facility
NEIDL National Emerging Infectious Diseases Laboratory
NEPA National Environmental Protection Act
NIAID National Institute of Allergy and Infectious Diseases
NIH National Institutes of Health
NIMBY Not in my back yard

NOLA New Orleans Louisiana
NPL National Priority List
NRC National Research Council
NRD Natural Resource Damages
OIE World Organization for Animal Health
PIADC Plum Island Animal Disease Center
PRA Probabilistic Risk Assessment
PTM Probabilistic Analysis of Post-Remediation Metal Loading Technical Memorandum (Revision 1)
QA Quality Assurance
QC Quality Control
 R_{ij} remedial action effectiveness
RA Risk Assessment
 RLP_j relative loading potential
ROD Record of Decision
RPM Risk Perception Management
SEC Stakeholder Engagement Committee
SPH Standard project hurricane
SOW Scope of Work
SSEIR Supplemental Final Environmental Impact Review
SSRA Site-Specific Risk Analysis
TCCR Transparent, Clear, Consistent and Reasonable
USACE U.S. Army Corps of Engineers
USAMRIID U.S. Army Medical Research Institute of Infectious Diseases
USDA United States Department of Agriculture
uSSRA Updated Site-Specific Risk Analysis
USNRC United States Nuclear Regulatory Commission

Chapter 1: Introduction

Risk assessment for large projects is expensive, time consuming, and practiced inconsistently by federal agencies. Studying six public projects and risk assessment approaches led to researching risk assessment processes. Public agencies use a variety of practices regarding uncertainty treatment, risk characterization, risk communication, and stakeholder perception management. Different approaches changes the decision-making value of the risk assessment process.

Analyzing six public cases of high-impact, low-frequency risks shows the decision-making value of each risk assessment. Each case is introduced through identification of the initial conditions of the risk assessment and associated risk management decisions. The analysis describes subsequent risk assessment and management changes, connecting how the risk assessment(s) informed the project risk management decisions. The concept of a Risk Perception Management (RPM) plan is introduced as a component to increase the decision-making value of the assessment process. The suggested RPM process iteratively captures stakeholder perceptions through the risk register to enable communication plan development for large, controversial projects, thus improving project stakeholder engagement.

1.1 Background

We talk about economic risk, health risk, accident risk, project risk, and weather risk (i.e. will I need an umbrella today?). Risk assessment and risk management occupy significant space across the social, news, and local media

outlets. Often the hazards identified in complex projects are related and dependent, although in practice many engineering risk assessments assume independence in the interest of reducing complexity.

Complex hazards necessitate comprehensive risk assessments. Risk assessment in federal agencies employs experts from a variety of fields assessing potential risks to the populace from natural, human health, environmental, ecological and economic hazards. Complexity of the hazards and their mitigation involves experts from multiple scientific disciplines. Risk assessment practice includes identifying hazards from a variety of sources, estimating their potential to occur, and developing plans to manage outcomes in the event the hazards materialize. Comprehensive risk assessments include experts from engineering, decision theory, economic theory, epidemiologic theory, ecologic theory, healthcare theory, and social and psychological theory.

Assessing hazards originated within the Environmental Protection Agency (EPA), the federal agency established by the passage of the 1970 National Environmental Protection Act. During the ensuing decades, risk assessment and management practice expanded across federal agencies responsible for human health, the environment, ecological management and federal facility projects. Independent reviews of federal risk assessments pervade the literature. Reviews of risk assessments describe common fundamental concerns unchanged since the early days of risk assessment within the federal government.

Problems identified within risk assessment critiques depend upon the nature of the hazard and consequences under evaluation. Common risk assessment issues

include varied treatments of uncertainty, limited risk engineering technology, narrowly focused hazards, limited expert resources and lack of available data (Machina, 1990; NRC, 1983; NRC, 1994; NRC, 2008).

The literature suggests solutions for risk assessment problems. Suggested solutions include involving stakeholders from the project initiation; presenting the uncertainty associated with the probability of hazards; collaboratively developing consistent risk assessment practices across agencies; iteratively assessing the hazard(s); considering the manner in which options are presented; and including the human tendencies regarding making arduous decisions (Anderson, 2003; Dourson & Patterson, 2003; EPA, 2000; Finkel, 1993; McClellan & North, 1994; Kleindorfer, Kunreuther, & Schoemaker, 1993; Hoch, Kunreuther, & Gunther, 2001; Morgan, Henrion, & Small, 1990).

1.2 Motivation

The variety of risk assessment processes of high-impact, low frequency hazards frequently contributes to project schedule delays. Experts suggest improvements to federal agencies regarding risk assessment methodology, processes, communication, and characterization, including specifically articulating subjective elements associated with uncertainty (Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997; NRC, 1983; EPA, 2000; EPA, 2003; NRC, 1994; NRC, 2008). Unfortunately, adoption of these suggestions remains inconsistent and incomplete (North, 2003; Mirer, 2003; NRC, 2008b; GAO, 2006; NRC, 2010c).

The repeated reviews of risk engineering assessment methods, implementation, practice, and skill within federal agencies motivates studying risk assessment processes utilized within six large, complex projects. High-impact, low-frequency hazards associated with these projects contributed to their selection for analysis.

1.3 Purpose of the Study & Research Questions

A valuable risk assessment informs complex decision-making. Communication and perceptions associated with assessing complex hazards impact decision making. Neglecting communication and perception management is analogous to solving half the problem. This study shows the connection between risk assessment processes and decision-making value for six large projects. Including risk communication management and perception management into the assessment process improves decision-making value.

Connecting original decisions to the initial risk assessment determines the initial value. The original risk assessment and associated risk management decisions are referenced by the term “initial conditions” in the context of this research. The initial conditions reflect whether the project risk assessment informs decision-making. Experts suggest iterating the project risk assessment serves to improve decision-making, with the caveat that the problem is articulated correctly at the outset (NRC, 1994; NRC, 2008).

1.4 Case Study Approach

Studying risk assessment approaches among diverse projects led to examination of the changes. Evaluating risk assessment changes, and the associated decision changes, led to selecting the case study research method. The case study enables a reflective, historical comparison between varieties of risk assessment approaches. The common processes in the cases include risk assessment iterations, subsequent independent evaluation and feedback of each iteration, and whether the updated risk assessment incorporated the recommendations, capturing stakeholder perceptions and communicated the risk assessment and analysis appropriately.

The research articulates the risk assessment approach for six large, complex projects. Each approach aligns to established risk assessment practice in varying degrees. Alignment to a process determined whether the approach informed initial decision-making for the project, establishing decision-making value of each approach. Table 1 Chronological Risk Assessment Reports chronologically lists the risk assessment processes germane to this study. Evaluating iterations of each project risk assessment, and whether the iterations incorporated reviewer feedback establishes risk assessment value. Development of a Risk Perception Management (RPM) plan involves establishing a risk perception register to capture stakeholders' perceptions associated with the hazards, increasing risk assessment decision-making value.

<i>Date</i>	<i>Title</i>	<i>Author/Publisher</i>	<i>Objective</i>
2010	Review of the	NRC	Review and evaluation of DHS

	Department of Homeland Security's Approach to Risk Analysis		risk assessment approach and capability; review the feasibility of an agency-wide risk assessment practice; and recommended risk assessments improvements.
2008	Science and Decisions	NRC	Update to the 1983 Red Book
2000	Risk Characterization Handbook	EPA	Articulated the qualities of good risk characterization: Transparent process, resulting in Clear, Consistent and Reasonable (TCCR) assessments informing policy.
1997	Framework for Environmental Health Risk Management	Presidential Commission on Risk Assessment and Risk Management	Broadened the definition of risk management. Articulated an iterative six-step framework for risk management
1996	Understanding Risk: Informing Decisions in a Democratic Society	NRC	Recommended an analytical-deliberative risk characterization process
1994	Science and Judgment in Risk Assessment	NRC	Balanced, critical analysis of EPA and the risk assessment methods inconsistently employed across the agency.
1993	Issues in Risk Assessment	NRC	Studied carcinogenic assessment and also a conceptual framework of ecological risk assessment.
1992	Framework for Ecological Risk Assessment	EPA	Similar to the ecological risk assessment framework in NRC 1993 with definitions and terminology differences.
1989	Improving Risk Communication	NRC	Discussed risk communication processes, messages, and improvements for communication.
1983	Risk Assessment in the Federal Government: Managing the Process	NRC	The Red Book outlined a four-step process for assessing health risks.

Table 1 Chronological Risk Assessment Reports

Chapter 2: Review of the Literature

The risk engineering analysis process within the federal government spans years of time and thousands of scholarly pieces contained within hundreds of

publications. Simply searching the risk engineering assessment literature returns tens of thousands of opportunities for study. The sheer magnitude of the literature suggests the depth and breadth of the risk engineering assessment field. The literature encompasses human health, environmental, ecological, infrastructural, natural, and man-made hazards across engineering, biological, societal and a litany of other fields. Risk engineering assessment literature relative to large, complex projects within the federal government bounds this study. The literature reviewed here illuminates the risk engineering assessment approach and risk analysis processes within federal agencies relative to large projects.

Passed in 1970, the National Environmental Policy Act (NEPA) established the Environmental Protection Agency (EPA) and required EPA to conduct an Environmental Impact Statement (EIS) for carcinogenic hazards to human or environmental health (EPA, 1970). In the decades since 1970, the practice of developing an EIS expanded across other agencies. Current EIS development occurs in a variety of contexts describing a litany of hazards and their potential impacts across federal agencies. Each agency employs varying depths of risk analysis, assessment and management skills for making decisions under uncertainty. The resulting risk analyses differ widely across agencies.

2.1 Definitions

Risk assessment practice contains terms of art: risk, uncertainty, probability, and risk assessment. These terms require defining because engineers misinterpret the

definitions. Misunderstanding the terms of art contributes to issues within risk assessment.

The Oxford English Dictionary defines “risk” as both a noun and verb. Oxford defines the noun as the “possibility of loss, injury, or other adverse or unwelcome circumstance”, and “chance or situation involving such a possibility” (Oxford University Press, 2013). The authoritative English language resource couples a hazard with its associated probability of occurrence. Oxford leaves little room for capturing the uncertainty associated with the probability of a hazard’s occurrence.

Turning again to Oxford for the definitions of “uncertainty” and “probability” further illuminates the problem associated with risk assessment practice. Oxford defines uncertainty as, “The quality of being uncertain in respect of duration, continuance, occurrence, etc.; liability to chance or accident. Also, the quality of being indeterminate as to magnitude or value; the amount of variation in a numerical result that is consistent with observation” (Oxford University Press, 2013). According to Oxford, understanding the concept of uncertainty is connected to the frequentist view of risk assessment. Few project stakeholders have motivation to count the observed occurrence of levee breaches, pathogen releases, hurricanes, or terrorist attacks.

Oxford defines probability as “the property or fact of being probable, esp. of being uncertain but more likely than not; the extent to which something is likely to happen or be the case; the appearance of truth, or likelihood of being realized, which a statement or event bears in the light of present evidence” (Oxford University Press,

2013). Further, Oxford provides the familiar definition of probability, “Math. As a measurable quantity: the extent to which a particular event is likely to occur, or a particular situation be the case, as measured by the relative frequency of occurrence of events of the same kind in the whole course of experience, and expressed by a number between 0 and 1” (Oxford University Press, 2013). Oxford describes the probability of an event as a measurable quantity. The connection between a probability and its likelihood is referred to as obsolete in Oxford’s definition. Referring to Oxford as a guide for risk assessment practice, therefore, the term “likelihood” should be avoided.

Probability contains associated variation. Oxford defines “variability”, “1. The fact or quality of being variable in some respect; tendency towards, capacity for variation, or change. 2. *spec.* a. The fact of, or capacity for, varying in amount, magnitude, or value. b. *Biol.* Capability in plants or animals in variation or deviation from a type.” Risk assessment practice utilizes the definition of 2.a. with respect to variability of the probability associated with a hazard’s occurrence.

The authority of the English language circularly references probability to its likelihood, without considering connecting uncertainty and probability. The missing defined connection between uncertainty and probability, coupled with the obsolete connection between probability and likelihood, contributes to misunderstanding of risk engineering analysis among experts, practitioners, project stakeholders, and the public community.

Hazards and their associated probabilities contain uncertainty regarding the probability. Practitioners struggle to understand differences between variability and

uncertainty associated with hazard probability. Experts understand these concepts a little more. Risk managers' limitations in understanding these concepts complicate selecting options. Hazard complexity further limits understanding. Complete understanding the probability of a hazard's occurrence coupled with the associated uncertainty and variability supports informed project decisions.

Definitions as Terms of Art (NRC, 1993; NRC, 1983; NRC, 2008; NRC, 1994):

1. Risk Engineering Process – the objective or subjective methods undertaken to identify and assess hazards, quantify the associated impacts, and describe mitigation options.
2. Risk Assessment – technical analysis of hazard probability, usually in estimated as a frequency, percentage, or probability between 0 and 1, and the associated hazards impacts. Risk Assessment should include uncertainty and variability of the assessment quantities.
3. Risk Management – process of decision-making among the variety of hazards mitigation options.
4. Aleatory Uncertainty – statistical probability associated with a hazard's occurrence, valid for high-frequency hazards and large sample sizes
5. Epistemic Uncertainty – degree of belief regarding the probability associated with a hazard's occurrence, especially associated with low-frequency hazards
6. Variability – the range associated with a frequency or probability

2.2 Genesis of Risk Assessment within Federal Agencies

In 1962 Rachel Carson authored the book *Silent Spring*, gaining recognition as a catalyst for raising public awareness regarding environmental hazards (Carson, 1962). In 1970 the Clean Air Act was passed, followed by the Clean Water Act two years later (EPA, 2014; EPA, 2014). EPA published risk assessment frameworks for hazardous environmental sites, water, air, and chemicals (EPA, 1987; EPA, 1989; EPA, 1992; EPA, 2000; EPA, 2003; EPA, 2004a). As a result, during the 1970's

awareness regarding carcinogenic human health hazards, air and water environmental hazards, and potential hazards within product and food supply chains increased.

The practice of engineering risk assessment has its roots in Probabilistic Risk Assessment (PRA) originally developed by NASA during the Apollo space program, after the fire in January 1967 which killed three astronauts (Bedford & Cooke, 2001). The roots of risk assessment practice originate within three contentious hazard sources: nuclear reactor safety; air pollution and ozone depletion (Morgan, Henrion, & Small, 1990).

2.2.1 Nuclear Reactor Safety

The initial public application of PRA occurred within the nuclear industry to assess nuclear power plant safety. The U.S. Atomic Energy Commission asked Norman C. Rasmussen, an MIT nuclear engineering professor, to assess the safety of light-water reactors. Dr. Rasmussen and a team of approximately 60 experts used event fault trees to develop reactor failure event sequences for two types of commercially available reactors. The probabilities of the log-normal distributions were estimated using stochastic simulation. The modeled consequences overlooked the inherent uncertainty within the models and assessment process. The resulting report became known as Wash-1400.

The scientific community of the mid-1970's reviewed the release of the Wash-1400 reactor safety study in 1975 study both favorably and critically (USNRC, 1975; Bedford & Cooke, 2001; Morgan, Henrion, & Small, 1990). Bedford and Cooke (2001) describe the reception of the study as "turbulent" within the scientific

community. EPA, the Union of Concerned Scientists, and other experts extensively reviewed the final draft, leading many scientists of the mid-1970's to publicly discount the application of PRA practice, and to question modeling uncertainty associated human behavior choices in the event of an accident (Bedford & Cooke, 2001). In 1975, Professor Harold Lewis led the American Physical Study of Wash-1400, questioning the validity of absolute probabilities in the report, and suggesting research into PRA methods (Morgan, Henrion, & Small, 1990). The Nuclear Regulatory Commission assessed Wash-1400 as an unreliable predictor of a reactor accident (Bedford & Cooke, 2001).

In 1977 Congress established a panel of nuclear experts, also led by Dr. Lewis, to review the study. The panel's report balanced validation of PRA practice against deficient treatment of probabilities within the Wash-1400 report. The resulting analysis concluded understatement of the uncertainty, and endorsed subjective probability methods contained within Wash-1400 (Bedford & Cooke, 2001).

Development of Wash-1400 as the authoritative source for PRA origination occurred over several years. Wash-1400 contributed to the application of risk assessment process within regulation of the nuclear industry. Additionally, Wash-1400 laid the foundation for the Nuclear Regulatory Commission to develop probabilistic safety objectives and safety goals which have continued to be utilized as practice of assessing U.S. nuclear power plants. Interestingly, in 1980, Dr. Lewis reported the root causes of the Three Mile Island accident were originally predicted within Wash-1400 PRA: human error, small accidental coolant losses, and transients

(Morgan, Henrion, & Small, 1990). The missing piece remains the inclusion of human uncertainty within the quantitative analyses (Bedford & Cooke, 2001).

2.2.2 Air Pollution

The Clean Air Act required the U.S. EPA to set and update standards for the quality of clean air, including setting criteria for air pollutants (Morgan, Henrion, & Small, 1990). EPA's original approach to compliance with the Act involved agency personnel reviewing the applicable literature within atmospheric and biological arenas and applying a "seat-of-the-pants" approach to make judgments about complex health issues (Morgan, Henrion, & Small, 1990, p. 9). Extending the approach to include expert elicitation regarding uncertainty resulted in controversy of questionable science associated with assessing pollution hazards (Morgan, Henrion, & Small, 1990).

Therefore, EPA established the Committee on Health Risk Assessment charged with developing an appropriate approach for air quality assessment. The resulting approach included expert elicitation developed by experts through contract work. EPA avoiding applying expert elicitation to policy decisions, instead using the approach to revise the assessment for airborne lead. EPA submitted the resulting assessment for review to the Clean Air Scientific Advisory Committee. Favorable review by the Committee enabled EPA to move forward with ozone risk assessment, although in smaller steps and at a slower pace. EPA maintains a backlog of assessments regarding air pollutants due to the controversy associated with subjective expert judgment (Morgan, Henrion, & Small, 1990).

2.2.3 Ozone and Chlorofluorocarbons

Ozone is a thin layer within the stratosphere which protects the earth from the sun's ultraviolet radiation. The National Academy of Sciences repeatedly studied the impact F-11 and F-12 chlorofluorocarbons have on ozone. These studies contain uncertainties associated with atmospheric transport, chemistry and loss volume; loss rates; and relationships between UV radiation and its biological effects. A 1979 study provided specific percentage numbers regarding the uncertainty, which many scientists question. The scientific community evaluating the 1979 report, and subsequent follow-up reports, point to iteratively examining the uncertainties associated with an evolving understanding of a complex problem.

2.3 Historical Successes, Failures, and Suggested Improvements

Risk assessment processes are inconsistent in federal agencies. In 1994, an NRC committee was unable to agree upon specific recommendations regarding principles or practices for EPA. The committee recommended the agency consider providing both quantitative and qualitative risk characterizations in verbal and mathematical forms (NRC, 1994). Further, the committee avoided recommending baseline risk assessment principles on which to base assessments. The experts suggested the process depended upon policy judgments, referring the agency to utilize the policy process to develop risk assessments.

The committee included other conflicting process suggestions, offering “plausible conservatism” to bridge understanding gaps, and the counter suggestion that risk assessments reflect current scientific understanding (McClellan & North,

1994; Finkel, 1993). The Committee articulated: “Model uncertainties result from an inability to determine which scientific theory is correct or what assumptions should be used to derive risk estimates”, indicating inability to reach consensus regarding appropriate risk assessment practice (NRC, 1994, p. 83).

In the absence of expert suggestions for consistent practice EPA developed risk assessment processes for health risks, pollution risks, cancer risks, ecologic risks and Superfund cleanup risks (EPA, 1992; EPA, 2004a; EPA, 1989; EPA, 2000). Thus, EPA became the *de facto* leader within the federal government singularly focused on the quantification of the probabilities and characterization of hazards (Goldman, 2003).

A risk assessment is defined as informative when the analysis provides value for making decisions, and the value can be verified (NRC, 1993; NRC, 1994; NRC, 2008). Risk assessment practice provided little confidence that the process informed the decisions at hand. The Department of Homeland Security (DHS) was encouraged to increase agency staff expertise (NRC, 2008b; NRC, 2010c). Two independent NRC review committees published critical reviews of the risk assessment DHS and the US Department of Agriculture (USDA) contracted regarding the National Bio- and Agro-Defense Facility (NBAF) in Kansas (NRC, 2010b; NRC, 2012). EPA published multiple risk assessment and risk characterization processes for environmental and toxicological hazards (EPA, 1989; EPA, 1992; EPA, 2000; EPA, 2003; EPA, 2004a). Risk assessment practice in federal agencies remains fragmented for carcinogens, pollutants and other human health hazards (NRC, 1994; Morgan, Henrion, & Small, 1990).

The need for quantitative analysis is pervasive in environmental risk assessment (EPA, 1987; EPA, 1989; EPA, 1992; EPA, 2004a). Experts maintain a critical reliance upon valid data to develop risk assessments from a frequency approach (Burke, 2003). Reliance upon data leaves little room for inclusion of risk assessment practice employing subjective methods. Subjective risk assessments are useful for infrequent hazards without historical record.

Recommendations to federal agencies regarding risk assessment include qualitative analysis, expert judgment, and policy trade-off analysis (Hattis & Goble, 2003; NRC, 1994). According to Hattis and Goble (2003) policy trade-off analysis refers to comprehensive comparison of the effects of each regulatory choice and its potential outcome.

Risk assessment is extensively applied throughout federal agencies, although academic risk assessment process research has been limited in its development. Risk assessment process regarding alternative methods for quantifying probability resulted in misalignment, because assessments failed to address the issue at hand (NRC, 2008; McClellan & North, 1994; Machina, 1990).

Lack of data was originally postulated as the primary issue within risk assessments (NRC, 1983). Today, incomplete treatment of uncertainty associated with risk assessment stands out as the overarching inconsistency across federal agencies (Mirer, 2003; Morgan, Henrion, & Small, 1990).

Limited understanding contributes to the problems associated with quantification of hazard probability and its associated uncertainty. Morgan and Henrion (1990) argue that objective uncertainties often tend toward overconfidence. They equate the

tendency toward overconfidence with subjective judgment, with equivalent credibility. As elements of making decisions and assessing risks, these underlying tendencies rarely surface in the assessment and risk management planning, thus leading to a suboptimal outcome (Hoch, Kunreuther, & Gunther, 2001).

The data used within federal agencies to inform decisions should align with the decision at hand (McClellan and North 1994; NRC 1983; NRC 2008). In practice, limited data available associated with an infrequent hazard can be shown to point to a particular desired decision, referred to by Morgan and Henrion as *reverse analysis* (Morgan, Henrion, & Small, 1990). In academic circles, limited data regarding infrequent hazards often cannot be independently validated and repeated, thus reducing the decision-making value of a risk assessment, resulting in experts' reliance upon judgment (EPA, 2003; Anderson, 2003; NRC, 1993). Depending upon judgment under uncertainty often creates consternation, churn, and evasiveness in decision-making, resulting in less robust decisions. Many risk assessment process approaches follow linear steps outlined in the 1983 Red Book (NRC, 1983). Modifying the process from a linear approach to iterative deliberation among stakeholders contributes to increased risk assessment value (NRC, 2008; Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997). Iteratively describing the problem, including stakeholder perceptions and judgments, and assumptions, increases risk assessment value for making decisions (Hoch, Kunreuther, & Gunther, 2001).

Originally described as an assessment of a hazard, a risk in the current complex environment of overlapping, integrated multi-disciplinary systems is

frequently over-, or worse, understated (USNRC, 1975; Crump, 2003; EPA, 2003; NRC, 1993; NRC, 2007; NRC, 2008). Decision makers often want as much data as can be mined, neglecting the important effort of initial problem articulation. Data mining leads to analysis paralysis, referencing the repeated search for more data. Thus the assessment provides little value to aid decisions (Machina, 1990; NRC, 2008). Data gathering, interpretation, and communication exercises employed to develop comprehensive risk assessments often lengthen projects, add unnecessarily to project costs, and, in many cases, are rarely revisited for verification purposes. Iteratively articulating the problem and potential alternatives and options, with all the stakeholders included, potentially reduces the costs and duration of conducting the risk assessment. In addition to technically assessing risks, capturing stakeholders' perceptions adds to assessment value (Kleindorfer, Kunreuther, & Schoemaker, 1993).

The risk assessment process should result in straightforward probabilities of the hazard(s) to improve understanding within the stakeholders and decision makers. Low-frequency, high impact risks quantified as minute numbers remain abstract and nebulous to most people (Hoch, Kunreuther, & Gunther, 2001).

With a goal of delivering a quantifiable risk assessment, the specific risk probability value, unfortunately, too often becomes the focus. To be useful, the risk assessment should address the problem, provided the problem is well-articulated from the beginning of the process. In today's climate of cross-functional, multi-disciplinary risk engineering science and assessment methodology, the NRC recommends iteration of the assessment of project hazards, with a goal of useful

decision-making and participation from all the stakeholders (NRC, 1993; NRC, 2008). The strength of the assessment, and its value for making decisions, often depends upon the openness of the agency to include all stakeholders across agencies with the goal of achieving stakeholder satisfaction and a valuable assessment (Finkel, 1993; De Rosa & Hansen, 2003).

2.4 The Red Book

In 1970 the federal government established the Environmental Protection Agency (EPA, 1970). Simultaneously, the National Environmental Protection Act (NEPA) required an Environmental Impact Statement (EIS) for all federal projects which could impact the environment. Few federal capital projects avoid impacting the human environment, thus federal agencies are required to conduct EIS's for projects before the project proceeds (Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997).

Each agency developed EIS assessment methods. In the early 1980's, confusing agency EIS methods prompted EPA to request the National Research Council (NRC) convene a committee of experts to develop a consistent method. The result was published in 1983. Titled *Risk Assessment in the Federal Government: Managing the Process* the publication became known as the Red Book (NRC, 1983).

The Red Book offered a four-step risk assessment process model. Additionally, the committee authors articulated the conceptual separation of risk analysis from risk management, and suggested the inclusion of "inference guidelines" to bridge gaps between available scientific data and subjective judgment of the

associated risk (NRC, 1983). Originally intended for cancerous hazards, the risk assessment process outlined in the Red Book has been adopted to varying degrees across federal agencies for assessing natural, ecological, environmental and in more recent years, terroristic hazards (EPA, 1987; NRC, 1994; NRC, 1996; NRC, 2008b; NRC, 2010c).

The Red Book articulated a four-step process of (1) identifying potential hazards, (2) quantifying the relationship between a potential dose of the hazard and the probability of an adverse effect (response), (3) quantifying potential exposures to the hazard, and (4) characterizing the associated risks of each dose-response/exposure scenario (NRC, 1983). Articulated in four steps, the Red Book process is:

1. Hazard Identification
2. Dose-Response Assessment
3. Exposure Assessment
4. Risk Characterization

An overarching concept within the Red Book is the conceptual separation of risk assessment and risk management (Davies C. J., 2003; Mirer, 2003; North, 2003; NRC, 1983). The NRC panel advocated the separation to avoid influencing the risk management options. As a result, EPA and other agencies developed organizational separations between assessment and management functions. The organizational separation between risk analysts and risk managers contributes to a communication gap, to the detriment of informing the process of decisions (GAO, 2009; EPA, 2000; Goldstein, 2003).

The Red Book identified the lack of data as the largest gap in risk analysis practice, a prevalent issue today (Anderson, 2003; Finkel, 1993; Machina, 1990;

NRC, 1983). Since 1983, several expert committees articulated updated risk assessment processes based upon the Red Book process, including subjective judgment considerations (EPA, 2000; NRC, 1994; NRC, 2008; Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997).

According to the original authors of the Red Book, the primary problem with risk assessment was the absence of data (NRC, 1983). The Red Book authors suggested using “inference defaults” to bridge the data gap with subjective expert judgment (NRC, 1983). This issue continues today (NRC, 2012; NRC, 2008). Ancillary problems associated with lack of data are analysis paralysis (NRC, 2008; NRC, 1994; EPA 2000); trying to obtain a singular, granular risk number (NRC, 2012; NRC, 2008b; NRC, 2008; NRC, 2010c); lack of proper risk analysis planning and insuring the risk analysis addresses the questions appropriately (NRC, 1994; NRC, 2008). Quantitative statistical analysis using the four steps outlined in the Red Book remains the standard of treatment for environmental assessments, although data availability remains a challenge.

2.4.1 Evolution of the Red Book process

The process outlined in the Red Book was adopted by many agencies to assess a variety of risks, including sociopolitical risk, ecologic risk, environmental risk, neurotoxicity risks and occupational hazards (Omenn, 2003; Slovic, 2003; Landis, 2003; Walker Jr., 2003; Wassell, 2003). The four-step process of the Red Book remains the standard for comprehensive risk assessment across federal agencies,

although implemented to varying degrees of sophistication (Burke, 2003; De Rosa & Hansen, 2003; EPA, 2003; NRC, 2008b; NRC, 2011; NRC, 1989).

Today the Red Book process within federal agencies depends upon the risk assessment resources and skills within each agency. For example, EPA has focused on hazards assessed with the skills of the staff available, leaving larger issues unaddressed (Weisburger, 2003). In other agencies, the Red Book is limited to a sociopolitical policy selection methodology, with little use for developing technical risk assessments (Slovic, 2003). In agencies charged with protection of human health the Red Book framework is utilized to varying degrees (Burke, 2003; EPA, 2002; EPA, 1989). Whether the original Red Book authors intended, other agencies have expanded using the Red Book process, looking to EPA as the leader in utilization and development of risk assessments (Doull, 2003; Landis, 2003; Burke, 2003; Walker Jr., 2003; Wassell, 2003).

2.4.2 Red Book Practice Across Agencies

The Bureau of Reclamation developed an agency-specific unique risk assessment process with respect to definitions, process and interpretation (Bureau of Reclamation, 2011). The Reclamation risk assessment process differs from the Red Book, using standard terms of art and an alternative methodology. The Reclamation risk assessment process is suited for low-frequency, high impact hazards associated with dams and levees falling under the agency's purview.

Reclamation wisely suggests a cross-disciplinary expert team develop the list of potential failure modes. The bureau further suggests a seasoned engineer serve as

the facilitator for articulating failure modes and assessing risks (Bureau of Reclamation, 2012). Limiting the facilitator role to an engineer assumes engineers are united to the risk assessment and subsequent risk management effort.

The Department of Homeland Security (DHS) risk assessment practice has come under recent scrutiny. DHS risk assessment skills lack maturity and expertise, relying heavily upon unfounded quantification of probability, and little treatment of associated uncertainty (GAO, 2009; NRC, 2008b; NRC, 2010c).

As experts recognized risk assessment issues extend beyond a lack of data, updates to the original Red Book framework have been proposed, including a place for judgment (EPA, 2002; EPA, 2003; NRC, 1994). EPA suggested Transparent, Clear, Concise, Relevant (TCCR) risk characterization (EPA, 2000). Other experts suggested an iterative, overlapping framework for dynamically assessing risks (Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997). In 2008, an NRC committee of experts suggested updating the Red Book process to include iterating risk assessments to validate the assessment's decision-making value (NRC, 2008).

2.4.3 *Red Book 2008 Update*

The original Red Book risk assessment process was expanded and modified in 2008, titled *Science and Decisions: Advancing Risk Assessment* (NRC, 2008).

Intending to strengthen the risk assessment process, the NRC recommended improving the original Red Book process to include all the stakeholders, articulate the

problem prior to assessing the hazards, and verify early in the process the planned assessment addressed the problem (NRC, 2008).

Selecting a course of action should occur after the assessment has first been confirmed as valuable and connected to the hazard. Process improvement suggestions included careful and transparent documentation of models, theories and assumptions. Stakeholders with a rudimentary understanding of the hazards should be able to follow the logical process of a transparent risk assessment (NRC, 2008).

The NRC expert authors suggested iterating three phases of problem formulation, assessment planning, and risk management. The three-phase process utilized stakeholder input to verify alignment of the selected project engineering risk assessment approach to the decisions at hand (NRC, 2008). Upheld by multiple NRC risk assessment independent review committees, the updated process has been referenced as the appropriate risk assessment process standard (NRC, 2010c; NRC, 2011b; NRC, 2012).

Recently agencies utilized the updated Red Book framework, achieving some success with their stakeholders (GAO, 2006; NRC, 2011b). Those who elect to ignore the 2008 recommendations do so at the expense of the project (CALFED Independent Review Panel, 2008; MWD, 2011; NRC, 2012; GAO, 2009).

Selecting a course of action should occur after the risk assessment has been vetted as useful and the stakeholders weigh the available options. Determination of a valuable risk assessment varies according to the needs of the project, the stakeholders, and the problem the assessment is designed to address. Foregoing a value determination of a risk assessment induces the potential of reaching a decision

disconnected from the problem. A good risk assessment process is one which includes all the stakeholders throughout and contains the following elements (NRC, 2008):

1. A clearly-articulated problem.
2. A plan to conduct the assessment, *including the identification of the appropriate levels of uncertainty and variability.*
3. The engineers conduct the risk assessment, per the Red Book four-step methodology, *including the relative risks and benefits between the decision options.*
4. The stakeholders confirm the value of the assessment, *including peer review alignment to the original plan (see item 2), and capacity to make a selection among the available options.*
5. The stakeholders weigh the merits of each option, select an option, and develop an appropriate plan for *communicating* the selected option.

The 2008 updated Red Book process contains a planning phase, an assessment phase, and a risk management phase, with an overarching provision for stakeholder involvement at all phases and at all stages (NRC, 2008). As an element of that process, the confirmation of the value of the risk assessment is in Phase II.

Confirming deliverables meet requirements reflects common project management practice. Figure 1 **Error! Reference source not found.** shows a flowchart suggesting modification of the 2008 process to include stakeholder risk perceptions within the risk assessment process. Including stakeholder risk perceptions increases risk assessment value for decision-making (Fischhoff &

Kadvany, 2011; Hoch, Kunreuther, & Gunther, 2001).

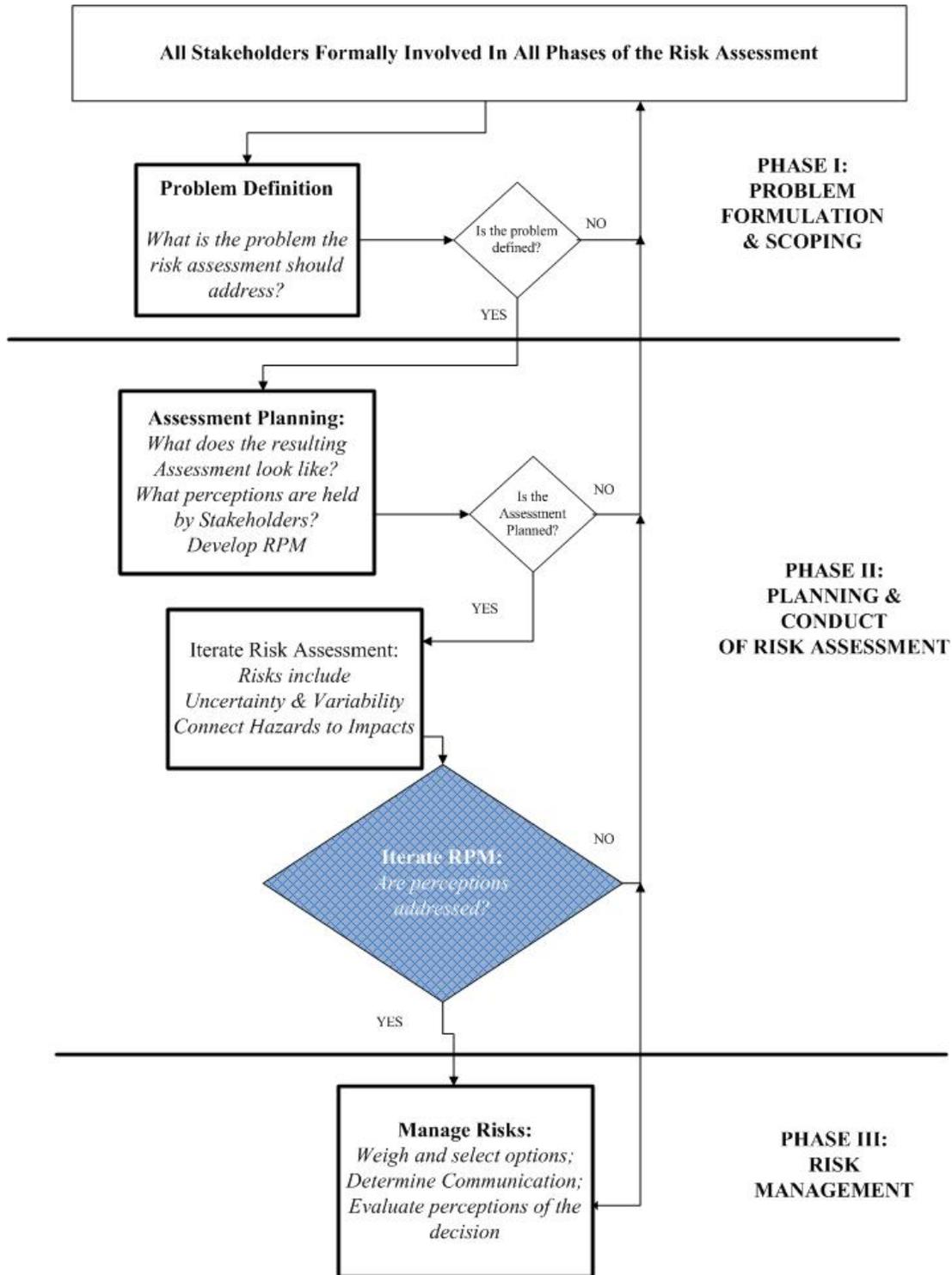


Figure 1 Flowchart of Iterative Red Book Process

This updated risk assessment methodology strengthens the original 1983 Red Book process in several ways (NRC, 2008; NRC, 1994). Including quantification of the uncertainty and variability is required (NRC, 2008; Morgan, Henrion, & Small, 1990). Iteration of the options is recommended (EPA, 2003; Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997). The problem requiring a risk assessment should be clearly articulated at the outset (NRC, 2008; Bedford & Cooke, 2001; Morgan, Henrion, & Small, 1990). Assessment of the relative risks should be the focus, instead of a singular risk probability value, percentage or quantity (Bedford & Cooke, 2001; Morgan, Henrion, & Small, 1990) .

Given the cross-disciplinary complex nature of the sciences within hazard assessment, the 2008 process update suggests closing the data gap through identification of uncertainty, variability, and conducting sensitivity analyses (NRC, 2008). Accounting for changes in uncertainty and variability originate from a variety of backgrounds, including game theory, decision science, Bayesian theory, and other more recently developed disciplines (Bedford & Cooke, 2001). Although advances within computing capacity, technical expertise, and project management practice, risk assessment practice continues in isolation, providing little value for large, complex projects with impactful, low frequency risks (Hoch, Kunreuther, & Gunther, 2001).

2.5 Engineering Risk Assessment Development within Federal Agencies

In parallel with the expansion of the utilization and application of the Red Book methodology throughout the EPA, the application of the risk assessment

framework and process expanded into other scientific areas, as well as into other federal agencies. Morgan and Henrion (1990) provide an informative summary of the genesis of risk assessment and its evolution within policy research and policy analysis, starting with practical applications by Howard at Stanford and Raiffa at Harvard during the 1960's across a broad range of areas such as seeding hurricanes, oil wildcatting, biocontamination of Mars by spacecraft, and risk of wildfires in the Santa Monica Mountains (Morgan, Henrion, & Small, 1990). The early work by Howard and Raiffa led to the expansion of decision science, and specifically treatment of uncertainty, into theoretical as well as practical arenas. Many privately-held and corporate firms employ analytical decision making methods into the development of corporate strategic initiatives and planning.

In addition to EPA, federal agencies such as the Nuclear Regulatory Commission (USNRC), Department of Energy (DOE), Department of Homeland Security (DHS), and others, regularly include treatments of uncertainty in risk assessments, although the degrees of completeness and specificity vary widely (Morgan, Henrion, & Small, 1990; Signature Science, LLC, 2012; DOE, July 2002).

Risk assessment practice has spread across federal agencies in more recent decades. Originally developed and established as fault-tree and event-tree analysis within the nuclear industry in the Wash-1400 report, the science of risk assessment evolved to include environmental, weather, human-health, animal health, and other hazards using multiple models and methods across a variety of scientific and social disciplines (USNRC, 1975; Dourson & Patterson, 2003; EPA, 2003; EPA, 1992; Hoch, Kunreuther, & Gunther, 2001; Fischhoff & Kadvany, 2011).

As complexity of the hazards increased, the expertise available within federal agencies to assess the risks and provide uncertainty estimates remained inconsistent (Burke, 2003; Davies J. C., 1993; GAO, 2006; Johnson B. L., 2003; NRC, 2008b). The Red Book articulated a conceptual separation between risk assessment and risk management, although the decision-making processes within federal agencies for complex large projects often remains incomplete due to organizational separation (Landy, Roberts, Thomas, & Nazar, 1990; NRC, 1993; North, 2003; NRC, 2012). The suggested conceptual separation between risk assessment and risk analysis within many federal agencies remains cavernous.

Hundreds of compounds remain on the assessment list within EPA (Mirer, 2003). The planned medical research facilities at Fort Detrick, MD and the initial risk assessment for the National Emerging Infectious Diseases Laboratories (NEIDL) in Boston were action/no-action assessments (NRC, 2011; NIH (RWDI West, Inc.), 2005). The risk assessments of the NBAF in Manhattan, KS provided little value regarding going forward with construction (NRC, 2010; NRC, 2012).

2.6 Current Practice

Today the practice of risk engineering analysis spans the gamut of scientific disciplines within engineering, decision and social sciences, business and management science, environmental and ecological science, and biological science. Many methods of conducting engineering risk assessments have been developed in the decades since Wash-1400 (Bedford & Cooke, 2001; Winkler, 2003).

The origins of risk assessment combine 40-plus years of scientists and engineers asking fundamental questions: What are the potential hazards? What is the likelihood of the hazard actually occurring? These are often extended into the risk management questions: Proactively, what plans are we going to put in place to prevent a hazard from occurring? What mitigations should be employed if a hazard occurs? Growth in the complexity of federal projects has expanded the risk analysis of large, complex, high-impact, and low-frequency hazards to include questions such as: Is the problem completely and clearly articulated? Are all the stakeholders at the table and involved in the decision process? What are the best decisions and how should managers decide? The additional complexity has given rise to the field of decision science and generated the study of the human decision-making process within the social sciences (Fischhoff & Kadvany, 2011; Hoch, Kunreuther, & Gunther, 2001).

The social scientists define decision selection process issues associated with underestimating probability called “anchoring bias” (Kleindorfer, Kunreuther, & Schoemaker, 1993). In 1974 Kahneman and Tversky demonstrated the anchoring bias when they asked two different groups of high school students to compute a product in ascending and descending order. One group computed $1 \times 2 \times 3 \times \dots \times 7 \times 8$. The second group computed the reverse order. Both groups should have obtained 40,320. Instead, the mean guess was 5412 for the ascending computation and 2250 for the descending computation (Kleindorfer, Kunreuther, & Schoemaker, 1993). This difference illustrates an example of cognitive bias impacting the risk assessment process, including subjective judgment employed across federal agencies today.

Risk assessment process improvements from social science experts includes questions into the assessment process such as: What anchoring biases, organizational silos, or hidden agendas are present in the evaluation of the risks? How does the assessment account for the different frames of reference among the stakeholders? How are stakeholders' perceptions changed throughout the risk assessment process? Addressing these recent questions suggests the inclusion of experts from other fields into the engineering risk assessment process (Hoch, Kunreuther, & Gunther, 2001; Kleindorfer, Kunreuther, & Schoemaker, 1993; Bedford & Cooke, 2001; Fischhoff & Kadavy, 2011; Landy, Roberts, Thomas, & Nazar, 1990; NRC, 2010; NRC, 2011c; NRC, 2010c; NRC, 2003).

Expanding the risk assessment process to include additional scientific perspectives admittedly increases time on the front end of a project schedule, yet as is the case in all pre-planning for project execution, potentially reduces the schedule and cost overall. The quantification of the magnitude of this suggested, and expected, cost reduction remains as future research.

Today, the problems remain the same as 30, or even 50, years ago. Recently stakeholders and engineers began to understand the complex nature of potential project hazards and associated management options. Experts consider options outside individual siloes of expertise, toward developing extensive engineering risk assessments inclusive of all stakeholders. Developing integrated, iterative risk assessments accounting for complexity enables the assessment process to withstand litigation, public scrutiny, and most important of all, expert peer review. The epitome

of this inclusive, integrated, iterative type of risk assessment is its use as a model for others.

2.7 Risk Assessment Value

Although mandated by federal agencies, many risk engineering analyses have provided little value for making decisions for many large federal projects (NRC, 1996; NRC, 1993; NRC, 1989; Burke, 2003; Crump, 2003; Finkel, 1993; Hattis & Goble, 2003). Some assessments however, have proven useful and are considered models for other risk analysis efforts. Although the process consumed ten years, the risk assessment of the National Emerging Infectious Diseases Laboratory (NEIDL) in Boston served as a model for the National Bio-and-Agro Defense Facility (NBAF) risk assessments (NRC, 2010b; NRC, 2012). The Interagency Performance Evaluation Task force (IPET) assessment was recognized as a model for the Delta Risk Management Strategy (DRMS) risk assessment (CALFED Independent Review Panel, 2008; NRC, 2011c). The National Research Council (NRC) maintains an extensive library of critical and also supportive risk engineering reports. Critical reports articulating process gaps and suggesting improvement options outnumber the library of analyses held up as process models for other engineering risk assessments.

Originally presented as a dose-response methodology to assess toxicology risks, the four-step risk assessment process articulated in the Red Book remains the practice within the federal government. Many agencies identify the hazards, and use technical modeling to provide a quantification of the potential risk associated with the

hazard. Individual agency implementation and maturity varies widely between the federal agencies.

Toward improving the process, the risk assessment framework has been extensively reviewed in recent years in the spirit of continuous improvement and improving the value of the project risk assessment deliverable. Risk assessments tend to provide a probability number, with little regard to the quantification of the associated uncertainty. Some assessments, as in the case of the initial NEIDL assessment, simply return the equivalent of a manufacturing practice “go/no-go” decision, a process used globally in manufacturing to assess whether a particular product meets its design requirements and thus is ready for consumer consumption (Johnson, M.D., 2003; NRC, 2011; NRC, 2010; NRC, 2010).

Chapter 3: Large Federal Projects Involving Complex Decisions

Establishing value of each final risk assessment deliverable involved comparing the initial risk assessment to the final project risk assessment. In this research comparison context, the initial hazards and decisions are referred to as “initial conditions”, indicating the identified hazards and management decisions the assessment was designed to inform. Stated in question form, the comparison became: Does the final risk assessment address the initial hazards? Does the final risk assessment address the initial management decisions? How are the final management decisions different from the initial management decisions? How is the project outcome affected by changes in the risk assessment deliverable? Risk assessment

value in this study stems from process changes and the associated impacts on decision-making capability.

3.1 Selected Cases and Criteria for Selection

The projects included in this study contained low-frequency, high-impact hazards. Additionally, the selected cases utilized the Red Book risk assessment process or the updated 2008 Red Book process (NRC, 1983; NRC, 2008).

Traditional statistical probability analysis, referred to as frequentist probability analysis, is applicable to large sample sizes. The cases in this study were chosen because the projects contain high-impact, low-frequency hazards. Many experts understand traditional statistical analysis is invalid in low-frequency spaces. Selected projects contained hazard probabilities with varying degrees of uncertainty. The stakeholders in complex cases are better served when the analysis is designed and planned using appropriate methods for the problem at hand (i.e. binary event and fault tree analysis; etc.). Experts suggest including variability and sensitivity analysis develops a comprehensive assessment (McClellan & North, 1994; Bedford & Cooke, 2001; NRC, 2008). The extensive literature offers assessment methods, including Monte Carlo, Bayesian, and other subjective models to assess low-frequency hazards (Bedford & Cooke, 2001; Winkler, 2003).

Table 2 lists six public projects with risk assessments selected for evaluation of risk assessment value. The table lists the date(s) of the risk assessment(s), the project title and its geographic location, the public agency responsible for the risk assessment, and the selection criteria for inclusion into this study. Representing the

spectrum of public projects which often polarize experts, community stakeholders, and the general public, the selected six projects include:

- Three biosafety level 3 and level 4 laboratories charged with researching vaccines for toxic pathogens;
- Two assessment projects regarding protective levee systems designed to provide ecologic and economic health and safety for broad geographic areas;
- One environmental cleanup Superfund site, the subject of expensive, intensive natural resource damages (NRD) litigation extending over many years and across state and federal boundaries.

The extensive literature regarding polarizing, high-risk project assessments provided many potential options for inclusion. Background and controversy associated with each project follows the tabular listing.

<i>Date(s)</i>	<i>Project Title</i>	<i>Location</i>	<i>Agency</i>	<i>Selection Criteria</i>
2001	Coeur d'Alene Superfund Site (CDA)	Coeur d'Alene, Idaho	Environmental Protection Agency (EPA)	Complex, litigious contamination cleanup due to uncontrolled mining operations over 100 years. Site remediation risk analysis published in 2001, followed by NRC review in 2005.
October 2005 – January 2008	Delta Risk Management Strategy (DRMS)	California Rivers Delta (San Joaquin and Sacramento Rivers)	California Legislature	Levee system risk analysis became political water management protocol.
2010-2011	Medical Countermeasures Test & Evaluation Facility (MCMT&E)	Fort Detrick, Maryland	US Army	Expansion of medical facility from hospital BSL-2 laboratory to BSL-4 laboratory.
2006-2008	Interagency Performance Evaluation Task Force (IPET)	New Orleans, Louisiana (NOLA)	US Army Corps of Engineers	Comprehensive risk analysis of NOLA levee system before, during and after Hurricane Katrina.

				Comprehensive technical analysis turned into communication project.
2010-2012	National Bio- and Agro-Defense Facility (NBAF)	Manhattan, Kansas	Department of Homeland Security (DHS)	DHS authorized RA of a new BSL-4 laboratory to study FMDv in the heart of livestock susceptible to the virus. RA conducted twice, with similar results and little progress.
2003-2014	National Emerging Infectious Diseases Laboratories (NEIDL)	Boston, Massachusetts	National Institutes of Health (NIH)	Model RA conducted over several years. BSL-4 laboratory as response to 9/11 events. RA became a political, communication, and public effort.

Table 2 Selected Cases

3.1.1 *National Bio- and Agro-Defense Facility (NBAF): Background and Controversy*

3.1.1.1 Background

After the terroristic events on September 11, 2001, the federal government created the Department of Homeland Security (DHS) responsible for intercepting, understanding and preventing future terrorist attacks (Bush, Presidential Directives, 2001). The 2004 Homeland Security Presidential Directive 9 (HSPD-9) authorized federal policy development to protect the agriculture and food chains from terrorists. Policy included surveillance, tracking, and laboratory infrastructure development for preventing and deterring animal and plant disease attacks (Bush, Presidential Directives, 2004).

Built in the 1950's, Plum Island Animal Disease Center (PIADC), located off the New York coast, has been the single location for developing bio- and agro-supply

defenses and mitigation efforts against infectious agents, including foot-and-mouth disease virus (FMDv) research. FMDv is the most highly-contagious known animal disease, infecting 100% of contaminated animals (GAO, 2008).

As a result of HSPD-9, DHS assessed PIADC insufficient and outdated for continuing research into bio- and ag-terroristic threats, zoonotic diseases, and infectious deadly disease vaccines, including FMDv (GAO, 2009). DHS selected Manhattan, Kansas for a new National Bio- and Agro-Defense Facility (NBAF) to develop vaccines against infectious agro- and bio-diseases and conduct research into zoonotic threats, including foot and mouth disease virus (FMDv) research (Federal Register, 2009).

Moving a BSL-4-ag research center from an island location to the mainland stirred significant controversy. The US eradicated FMDv from the mainland in 1929, achieving FMDv-free status (GAO, 2008). The GAO estimated economic losses potentially more than \$6 billion, based upon 2007 agricultural economic sector. Today losses could be higher, as agriculture has expanded during the past seven years. According to the US Farm Bureau, agriculture exports totaled \$115 billion worldwide in 2010, indicating the US a net agriculture exporter (American Farm Bureau Federation, 2014). Risks associated with DHS conducting FMDv research on the US mainland concerns many stakeholders at the local, state and national levels.

3.1.1.2 Controversy

3.2 *Historical Controversy*

Controversy associated with the NBAF project began in 2007 when DHS published the NBAF Notice of Intent regarding moving forward to develop an EIS and select the NBAF site (GPO, 2007). The GAO reviewed the EIS, responding with a critical assessment questioning DHS capability to safely conduct FMDv research on the U.S. mainland, noting the last outbreak of FMDv in 1929 in the U.S., and multiple risk analysis gaps regarding modeling, assumptions, and assessment processes (GAO, 2008; GAO, 2009). DHS responded, indicating in the Notice of Availability the preferred site alternative of Manhattan, KS for the NBAF and the Final EIS (FEIS) (DHS, 2008).

Two Kansas websites contain evidence regarding community polarization surrounding the NBAF. Concerned citizens established a website contesting the NBAF plans, and politicians established the website supporting NBAF (Concerned Citizens, 2008; State of Kansas, 2009). Both websites contain compelling localized arguments supporting their respective positions. The development of community-based websites suggests deeply-held perceptions by supports and detractors, and questionable credibility of the EIS.

Federal and state stakeholders raised comprehensive risk assessment practice and safety questions, including whether FMDv research could be conducted as safely on the mainland as on an island (GAO, 2008; GAO, 2009). Kansas stakeholders raised

FMDv-specific questions regarding processes to prevent a potential FMDv outbreak, establishing a website documenting their concerns (Concerned Citizens, 2008).

Congress connected releasing NBAF funding to independent NRC review of DHS-contracted risk assessments. In addition to the EIS, DHS delivered two site-specific risk assessments (SSRA). Twice NRC experts questioned the technical risk assessment skills within each deliverable (NRC, 2010b; NRC, 2012).

The committee indicated the first SSRA was a “notable first step in an iterative process”, identifying multiple significant shortcomings (NRC, 2010, p. 2). An updated SSRA followed the initial SSRA and subsequent NRC review (Signature Science, LLC, 2012). The NRC found similar gaps within the SSRA and the subsequent uSSRA regarding technical analyses and modeling methods employed in both efforts (Signature Science, LLC, 2012; NRC, 2010b; NRC, 2012).

NBAF in Chapter 3 contains a comprehensive discussion of the SSRA and uSSRA, developing a connection between NBAF assessments, community concerns and the risk assessment processes employed. DHS addressed community concerns through development of a “Stakeholder Engagement Plan” specifically to address risk communication to the public and critical stakeholders (Signature Science LLC, 2010).

Other efforts in parallel with NBAF risk assessment suggest NBAF controversy at the federal level. An NRC committee reviewed DHS technical risk assessment capability, documenting risk assessment skill gaps within agency staff (NRC, 2010c). As recently as fall 2013, the U.S. House of Representatives questioned NBAF safety, as well as the project cost (U.S. House of Representatives, 2013). Throughout the NBAF planning phases, questions abounded regarding BSL-4 Ag safety relative to

FMDv research and potential release on the mainland, as well as questioning DHS risk assessment capability.

3.3 Current Controversy

Amid this tenuous controversy, Kansas and Congressional politicians broke ground in May 2013 to begin construction of the NBAF utility plant (State of Kansas, 2009). In fall 2013, the US House removed \$400 million in NBAF funding from the budget (U.S. House of Representatives, 2013). However, in January 2014, Representative Hal Rogers, Chairman of the House Appropriations Committee, restored \$400 million into the federal budget for NBAF construction (U.S. House of Representatives, 2014).

3.3.1 NEIDL: Background and Controversy

The National Institutes of Health (NIH) biodefense research agenda expanded in the wake of September 11, 2001 events. A division of NIH, the National Institute of Allergy and Infectious Diseases' (NIAID) assessed the need for national laboratories to develop new methods of treating, preventing, and diagnosing a variety of bacterial and viral diseases which could be used as bioterrorist pathogens. Diseases and pathogens to be studied include viruses (e.g., Ebola, Marburg, dengue fever, Lassa fever, and highly pathogenic influenza) and bacteria (e.g., *Shigella* and plague). In 2003, the NIH awarded a \$128 million grant to Boston University and the Boston University Medical Center to design and build the National Emerging Infectious Diseases Laboratories (NEIDL) facility designated to address biodefense research (NIH, 2003; NRC, 2007).

The NEIDL facility includes a biosafety level 4 (BSL-4) containment laboratory housed in a 192,000 square foot building. The BSL-4 laboratory has been the primary source of community controversy associated with the facility, although the footprint of the BSL-4 space reflects 13 percent of the building (NRC, 2011b). Contributing to the controversy, the facility location in Boston's South End is an environmental justice community (NRC, 2011b). In addition to extensive public meetings regarding the facility operational safety and NIMBY syndrome, three legal actions challenged the project.

NEIDL involves a complex timeline of community concerns, NIH risk assessments, and lawsuits. According to the Boston Bar Association, approvals from the City of Boston and the Commonwealth of Massachusetts were granted in fall 2004, without full disclosure from BU regarding three lab workers infected with tularemia. The two-week delay from October 29 to November 9 between tularemia infection and state health department notification violated state laws. The Boston Redevelopment Authority (BRA) also violated state laws when they transferred the land to BU in December 2004 without an appropriate finding under Section 61 of the state environmental statute (Boston Bar Association, 2014). Learning about the tularemia infection in January 2005, and the land transfer without following MEPA guidelines, led to the first lawsuit *Ten Residents vs. BRA*. A civil rights complaint was filed in July 2005 alleging the South End location discriminated against neighbors of color who were already disadvantaged. Both suits were represented *pro bono* by counsel (Boston Bar Association, 2014).

NIH released the Final Environmental Impact Statement (FEIS) in December 2005. The FEIS analysis considered two approaches, action and no action. RWDI West, Inc. developed the risk assessment focused on anthrax spore release and dispersion, using modeling techniques developed by Lawrence Livermore National Laboratory (LLNL) (NIH (RWDI West, Inc.), 2005). In spite of the lawsuits, the record of decision to proceed with construction was published in the Federal Register in February 2006.

Community stakeholders found the FEIS and Record of Decision (ROD) inadequate regarding the risks associated with BSL-4 research in a metro areas. As a result, the Boston Bar Association Committee for Civil Rights Under Law filed a lawsuit in U.S. District Court alleging NEPA violation, *Allen vs. NIH*, in May 2006. In July 2006, in *Ten Residents vs. BRA*, state court concurred with the community, finding the FEIS fell short in several areas. Judge Gants in the case indicated NIH failed to consider the risks associated with building the NEIDL in alternative locations, failed to consider the risks associated with a worst-case pathogen release and infection scenario, remanded prior project approvals to originating agencies, vacated prior decisions based upon the original FEIS, and ordered a new Supplemental Final EIR to comply with NEPA requirements (Boston Bar Association, 2014).

Subsequently during Fall 2006, NIH and Judge Saris argued the merits of *Allen vs. NIH*. In September, NIH suggested a new environmental impact review was unnecessary because of Judge Gants' similar orders in *Ten Residents vs. BRA*. NIH neglected to inform Judge Saris of the forthcoming appeal in that case, however. In

October, Judge Saris ruled NIH had to inform the Court and Plaintiffs at least 60 days before conducting any BSL-4 research. In December, NIH indicated to Judge Saris the agency intended to avoid NEPA compliance of the SFEIR ordered by Judge Gants, indicating the review was voluntary. Indicating her agreement with Judge Gants regarding inadequacies, Judge Saris ordered the forthcoming supplemental review to comply with NEPA. In January 2007 NIH informed Judge Saris the supplemental environmental impact review ordered by Judge Gants and endorsed by Judge Saris would comply with NEPA (Boston Bar Association, 2014).

According to the Boston Bar Association, in April 2007 NIH demonstrated additional efforts to manipulate the information system when the Boston Globe reported a fire in a BU BSL-3 lab which occurred in March, including BU's failure to notify the state health department. The state agency learned about the fire "incidentally", instead of BU reporting it directly (Boston Bar Association, 2014). In August 2007, in compliance with NEPA and court orders, NIH released the Draft Supplementary Risk Assessment and Site Suitability Analysis (DSRASSA), followed by a tenuous public comment period. A four-hour public meeting opposing the NEIDL, followed one month later by a five-hour hearing in the U.S. House of Representatives questioning the funding and risks of labs such as NEIDL, resulted in the Massachusetts Executive Office of Energy and Environmental Affairs contract with NRC to review the NEIDL DSRASSA. The NRC review published in November indicated the DSRASSA was unsound and incredible. On December 13, 2007, the Supreme Judicial Court in *Ten Residents vs. BRA* unanimously confirmed Judge Gants' findings, ordering NIH to submit to the Commonwealth, another, now

third, new supplemental environmental impact report. One week following this ruling, on December 20, 2007, Judge Saris in *King vs. Office of Civil Rights*, ordered the Office of Civil Rights to begin investigating the discrimination claims, and to issue a decision no later than 90 days following the final NIH environmental report (Boston Bar Association, 2014). Clearly the action/no action alternative in the original FEIS, and subsequent draft supplemental risk assessment, fell embarrassingly short.

In the wake of the legal actions, NIH established a Blue Ribbon Panel (BRP) of independent experts in March 2008. The BRP advised the agency regarding the scope of the recently mandated additional risk assessments. The BRP suggested NIH conduct additional work regarding the risk assessments, including using validated scientific methodologies; epidemiologic data; community characteristics; insuring transparency of the process, methodology, results and final assessment interpretation; and improving risk communication (Tetra Tech, Inc., 2009).

The BRP developed a Scope of Work (SOW) authorizing Tetra Tech, Inc. to provide updated additional risk analyses necessary to comply with the court's and NRC's recommendations (NIH Blue Ribbon Panel, 2008). BRP suggestions regarding risk communication resulted in extending the risk assessment process to include additional analysis and feedback from the NRC review committee. Based upon this suggestion, NIH requested NRC risk assessment review and feedback at specific completion points throughout the process (NRC, 2010). The Tetra Tech SOW contract stipulated risk assessment deliverables at the 25%, 50%, 75%, 90% and 100% completion stages, including appropriate public comment periods, with

completion by June 30, 2010, seven years after NIH awarded the initial construction grant.

Beginning in 2008, NIH demonstrated commitment to a transparent process and cultivating community stakeholder support throughout the remaining NEIDL process. NIH demonstrated transparency by establishing the BRP and implementing their improvement suggestions; by requesting NRC review of the risk assessments; by submitting multiple risk assessments to public scrutiny and feedback; and by including community perspectives into the risk assessment process.

For example, pathogen release scenarios included within the risk assessment originated from NRC review, public comments, and courts. The 2008 Statement of Work contained 13 release scenarios: eight from public comment, six from NRC review, two simultaneously suggested by NRC reviewers and community stakeholders' comments, and two suggested by the courts. Figure 2 lists the types of scenarios NIH included into the risk assessment process, with an example of each type. The examples are not intended to be extensive or exhaustive. The figure shows NIH assessed release events from the stakeholder perspectives, demonstrating agency commitment to risk communication by listening to the stakeholders, capturing their concerns, and addressing each type of release scenario within the risk assessment process.

Type of Scenario	Examples	Source of scenario
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		Public (8)	NRC (6)	Federal Court (1)	State Court (1)
Mechanical or power failure	Lab equipment failure		x		
	Loss of electrical power	x			
	Malfunction of solid and liquid waste disposal systems	x			
Transportation accident	Transportation accident			x	
Security failure	Site security failure		x		
	Personnel security failure		x		
Release via fomites or vectors	Fomites contaminated with transmissible agents	x			
	Release of vector-borne agent	x	x		
Human error	Procedural errors resulting in inadvertent infection (e.g., mislabeled tubes)	x	x		
	Infection not diagnosed early and spreads in community, esp. via public transportation	x			
Malevolent actions	Malevolent action		x		x
	Suicide bomber, airplane attack, truck with explosives, fire	x			
	Disgruntled or deranged lab worker spreads agents in community	x			

Figure 2 Overview of Scenarios with Quantity of Sources

3.3.2 Fort Detrick: Background and Controversy

Congress mandated expanding the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) high-containment facilities as part of the National Interagency Biodefense Campus at Fort Detrick in Frederick, Maryland (NRC, 2010d). These facilities are responsible for handling infectious pathogens, which can

cause potentially lethal diseases. The USAMRIID Final EIS was published in December 2006, followed by the Record of Decision to construct the laboratory in February 2007 (NRC, 2010d). This facility was followed by the Medical Countermeasures Test & Evaluation Facility (MCMT&E), also located at Fort Detrick (NRC, 2011).

The USAMRIID neighbors publicly opposed the expansion of additional laboratory space for research on potentially lethal agents. Due to this opposition, Congress mandated the Secretary of Defense commission a National Research Council study of the required Environmental Impact Statement (EIS) (NRC, 2010d).

The NRC committee evaluated three elements of the EIS: the credibility and mitigation from a scientific perspective of the health and safety risks; USAMRIID's procedures for reducing exposure to pathogens, and alignment of those procedures with Center for Disease Control (CDC) and NIH procedures; and review infections acquired in the current laboratory as a lessons learned exercise for the proposed laboratory and proposed procedures. The neighbors were fearfully aware of prior laboratory-acquired infections (LAIs) at Fort Detrick, contributing to apprehension regarding facility expansion (NRC, 2010).

Based upon the USAMRIID process and feedback, the Army requested NRC review of the site-specific risk assessment work plan for the MCMT&E (NRC, 2011). NRC input included reviewing the proposed risk assessment work plans, as well as pathogen selection information, release scenarios, and infection models. The committee was asked to review early quantitative and qualitative risk assessment models and results, if available. The committee review was limited to assessing the

adequacy and validity of proposed risk-assessment methodology and draft results for inclusion into the MCMT&E EIS. The committee was not permitted to assess the EIS as a whole, nor the safety of the facility. Interestingly, the Army requested reconvening the USAMRIID review committee to evaluate the risk assessment plans for the MCMT&E facility.

The Fort Detrick laboratory was selected for inclusion into this study because the Army recognized deficiencies in its risk assessment process. The USAMRIID EIS was reviewed based upon Congressional mandate, while the MCMT&E risk assessment plans were reviewed. This combination of review timing components reflects issues associated with both NBAF and NEIDL, contributing to the value of Fort Detrick for this research. Met with opposition similar to NBAF and NEIDL, the Fort Detrick expansion pressed forward with little regard to community stakeholder concerns, NRC review feedback, and no litigation.

3.3.3 IPET: Background and Controversy

New Orleans, Gulf Coast and Lake Pontchartrain hurricane protection history involves complex environmental, economic, public and private stakeholders collaborating for over 50 years regarding a comprehensive protection system (NRC, 2006). The protection system evolved after Hurricane Betsy in 1965, a storm which killed 75 people and caused billions of dollars in damages. Congress authorized development of the hurricane protection system funded through federal, state and local resources (NRC, 2006). A complex partner network developed and maintain the

levees, dams, and canals designed to protect swaths of public, private, urban and wetland infrastructure and lives (NRC, 2006).

The U.S. Army Corps of Engineers (USACE) maintains responsibility for hurricane protection project design and construction through contracts awarded to a host of private firms. After construction, local authorities assume maintenance responsibilities. USACE developed and constructed approximately 125 miles of protective levees, canals, floodwalls and other protective infrastructure along the Gulf Coast, turning management over to local entities upon completion. The protection system reflects a complex system of varying capacities, resources, mandates, with different historical decisions and prior conditions (NRC, 2006).

On August 29, 2005, Hurricane Katrina devastated the Gulf Coast in Louisiana and Mississippi. The 17th Street and London Avenue canals were breached, levees overtopped and Lake Pontchartrain water levels elevated (NRC, 2006).

Flood damage in the New Orleans-Gulf Coast geographic area amounted to hundreds of lives lost and billions of dollars in damages. The storm generated a 28-foot storm surge and 55-foot waves (USACE, 2014). According to the USACE, the damage wrought by the storm was unprecedented. Approximately 80% of New Orleans was flooded to depths exceeding 15 feet in many areas. Surge and waves caused 50 major levee breaches in the regional Hurricane and Storm Damage Risk Reduction System (HSDRRS). Thirty-four of the city's 71 pumping stations were damaged, and 169 of the system's 350 miles of protective structures were compromised. Also contributing to the flooding was heavy rainfall: 14 inches in a 24-

hour period. More than 1,500 lives were lost. According to the Federal Emergency Management Agency, Katrina is costliest disaster ever to occur in the United States, ranking as one of the largest natural disasters in U.S. history (USACE, 2014; NRC, 2006).

In October 2005 the US Army Corps of Engineers (USACE) commissioned the Interagency Performance Evaluation Task Force (IPET) to conduct a technical root-cause investigation to understand what happened during Katrina, with the goal to apply lessons learned to the rebuilding of levees and other protection structures in and around New Orleans (NRC, 2006). In addition to developing and applying risk assessment practices to understand the risks from hurricane-induced flooding, the Corps of Engineers also requested the IPET team estimate risk after the new 100-year hurricane storm damage reduction system (HSDRRS) was scheduled for completion in approximately June 2007 (NRC, 2006).

The IPET team effort resulted in an engineering-based risk assessment for New Orleans and vicinity. IPET released flood-depth maps reflecting pumping capabilities at three points in time: prior to Katrina, 2007 post-Katrina and 2011 post-Katrina. Further, the maps reflected expected property damage risk and loss of life at each frequency.

Communicating associated risks for general public consumption and understanding involved risk communication concepts and strategies. The resulting comprehensive risk assessment in general and technical terms enabled the stakeholders to ascertain the overall picture of the risk situation for New Orleans (Link, et al. 2009).

The IPET risk assessment combines technical engineering risk assessment and risk communication practices, lending to its inclusion in this research. IPET demonstrates using communication concepts and social theories regarding public understanding of complex information. IPET is an outstanding example of technical comprehensive risk assessment dovetailed with comprehensive communication methods designed to improve public risk perception of hazards.

3.3.4 *DRMS: Background and Controversy*

Including the DRMS assessment into the research is based upon the evolution of the state-legislated Delta levee system assessment into a comprehensive questionable plan. DRMS began as reactionary legislation in California to understand vulnerability within the Delta levee system after Hurricane Katrina devastated New Orleans. The DRMS levee risk assessment expanded into the political arena surrounding access to scarce, clean water.

The DRMS story involves the assessment of 1300 miles of California Delta levees to simultaneously withstand breaches and provide clean water to California residents, without ecological damage to animal and plant habitat. The levees and the Delta waters they protect provide life-giving water to people, land and aquatic animals, and plants across most of the state of California. Two out of three people in California receive water from the Delta (DWR, 2009). Since 1900, 158 levee failures have flooded Delta islands (DWR, 2009). Subsidence has reduced Delta islands to as much as 25 feet below sea level (DWR, 2009).

3.3.4.1 California Delta Background

The San Joaquin and Sacramento rivers meet east of San Francisco Bay forming a delta region of approximately 700,000 acres protected by over 1100 miles of levees. Originally built in the mid-1800's 3 to 5 feet tall, today many are 15 to 20 feet tall. Over time, due to peat soil characteristics in the Delta, many of these levees have changed due to subsiding (eroding), seepage, compaction and other continual changes within the Delta region (DWR, 2009; Lund J. , et al., 2008; Lund J. , et al., 2010; NRC, 2012).

The Corps of Engineers manages 385 miles within the levee system, leaving the majority, over 730 miles, to public-private management sharing maintenance costs between the state of California and the local landowners (DWR, 2013).

Protecting and improving the levee system remains critical because two-thirds of all the residents of California depend upon the Delta for drinking water. Historic and future potential breaches due to wear, earthquakes, storms and rising sea levels threaten the Delta and its myriad of inhabitants.

3.3.4.2 Controversy

The state established competing yet co-equal goals of restoration and also usage of a scarce water resource and its ecosystem, increasing complexity regarding levee risk assessment policy and decisions (Lund J. , et al., 2008; Lund J. , et al., 2010) . According to one report, the current system of usage and maintenance supporting the Delta is not sustainable (Lund et al., 2008). The levees, originally constructed over a period of years between the late 1800's and early 1900's, suffer from subsidence (erosion), and disjointed ownership and maintenance. The levee

system conveys Delta water to the arid southern California regions. The Delta controversy includes varying water management, conveyance, and ecological system health perspectives from a variety of stakeholders across a broad geographic area. Stakes are high should the Delta levee system incur damage similar to the damage wrought by Katrina upon New Orleans.

Potential levee failure consequences runs into the billions of dollars and hazards to millions of people (Lund J. , et al., 2008). Exporting Delta water to southern California results in water quality deterioration within the Delta and its system (NRC, 2012a). The potential flooding threat in the event of a levee breach remains constant (Lund J. , et al., 2010). Many experts in recent years share the view of a hazard of when, not if, and the unsustainable efforts to provide scarce water resources to the southern California areas (Lund J. , et al., 2010; Lund J. , et al., 2008). These conflicting demands upon Delta water remain unresolved.

The state of California specified co-equal, conflicting Delta goals of ecological management for nature's benefit, and providing water for human benefit (Delta Vision Blue Ribbon Panel, 2013). Understanding complex Delta issues led to a group of volunteer Delta landowners starting a website, in response to a Delta Vision meeting during which DWR presented questionable information (Delta Landowners, 2014). Levee risks are critically important, yet the underlying current of conflict between ecology and human sustainability remains unresolved.

3.3.4.3 DRMS Background

In August of 2005 Hurricane Katrina struck New Orleans and the Mississippi Delta Gulf Coast. Thousands of lives were lost, billions of dollars of

damage occurred, and the levees, originally designed to protect New Orleans and her residents, failed such that sections of the city sustained dramatic devastation (Link, et al., 2009).

As a result of the Louisiana devastation, the California legislature recognized their constituents' vulnerability due to the instability of the Delta levee system. Reacting to the devastation in the New Orleans-area hurricane protection system, the state of California passed Assembly Bill 1200 (AB 1200) in 2005. The legislation required the California Department of Water Resources to assess Delta levees regarding 50-, 100-, and 200-year projections due to potential impacts from floods, earthquakes, and subsidence and climate changes, including combinations of those impacts (California Legislature, 2005). The bill further required the Department of Water Resources and the Department of Fish and Game to collaboratively evaluate mitigation options to meet the legislated objectives associated with the two rivers and the Delta, culminating in a report due no later than January 1, 2008.

The nine objectives for the levee system assessment contained in the bill, include (California Legislature, 2005):

1. Prevent supply disruption
2. Improve drinking water quality
3. Reduce the salts
4. Maintain delta water quality
5. Preserve the delta lands
6. Protect water rights
7. Protect infrastructure
8. Preserve, protect and improve the levees
9. Department of Fish and Game provide a rating of each option from the perspective of restoring salmon and other fish in the Delta and rivers' estuary systems.

The Delta Risk Management Strategy (DRMS) report, issued in January 2008, summarized the legislated objectives this way (CALFED Independent Review Panel, 2008):

- Impacts of levee failures on water supplies within the Delta due to subsidence, earthquakes, floods and sea level rise (i.e. climate change)
- Options to reduce the impacts of these hazards
- Options to restore salmon and other fish in the Delta

In addition to the levee system assessment through the DRMS effort, the State of California established multi-pronged, some might argue duplicative, committee efforts to understand the Delta ecosystem and water supply issues, including consideration of other options for risk mitigation, water quality improvements, and Delta management strategies and plans.

DRMS was established to assess levees, projecting failure consequences balanced with maintaining and improving water quality (California Legislature, 2005). CALFED established the Ecosystem Restoration Program (ERP) Conservation Strategy to understand and evaluate potential restoration methods based upon evaluation of soils, habitats and fish species requirements (MWD, 2011). The governor established the Delta Vision to develop a sustainable management vision and plan for the Delta to balance the economic and social needs of the state against the environmental ecosystem needs within the Delta for sustainability (California Departments of Water Resources and Fish and Game, 2008). The Bay Delta Conservation Plan (BDCP) evaluated the Delta from the perspective of the water operations permitting process with the goal of protection and restoration of endangered or at-risk species (NRC, 2011). On the receiving side of water exports

from the Delta, the Southern California Metropolitan Water District (MWD) noted these four groups charged with similar objectives working in isolation resulted in controversial political paralysis (Lund J. , et al., 2010; MWD, 2011).

The interconnectivity between multiple parallel assessment and planning efforts against the backdrop of clean consumable water, coupled with minimizing disruption to community infrastructure in the event of a hazard, led one reviewer to suggest comprehensive collaboration to develop understanding of the risks and possible mitigation options (MWD, 2011). Delta levee breaches had occurred, and would continue to occur. DRMS controversy revolved around the politics of water provision balanced against the co-equal goal of environmental protection, in the spotlight of recent Katrina catastrophic damage in New Orleans due to levee breaches.

According to the CALFED Independent Review Panel (IRP) who reviewed DRMS deliverables, and other experts, controversy involves varying perspectives, mandates, investigative and operational conflicts regarding Delta water resources (CALFED Independent Review Panel, 2007; Lund J. , et al., 2008; Lund J. , et al., 2010). Southern California residents rely upon water exported from the Delta. Delta farmers rely on the water locally to support farming enterprises. Levees constructed over 100 years to a variety of specifications fail, resulting in flooding and requiring costly repairs. Several endangered fish species face potential extinction due to the water usage and management practices. The state mandated providing water for man's benefit and nature's benefit as co-equal goals, contributing to the controversy (Lund J. , et al., 2008).

Levee risk assessment involved political considerations and contention, which led to DRMS inclusion into this study. The initial levee assessment became mired in political resource management processes for a scarce, life- and livelihood-sustaining resource. Efforts to mitigate levee risks, based upon Hurricane Katrina in 2005, remain one component of solving the variety of conflicting controversial sustainment and preservation issues associated with executing the co-equal Delta management goals.

3.3.5 Coeur d' Alene: Background and Controversy

The Coeur d' Alene River Basin is a mountain stream flowing 166 miles across the panhandle of Idaho. Originating in the Bitterroot Mountain Range on the border between Idaho and Montana, the south fork of the river courses westward in narrow valleys through steep mountains, lush valleys, vibrant wetlands, joining with the north fork and continuing for another 70 miles, eventually emptying into Lake Coeur d'Alene.

The lake is 25 miles long, and is drained on the north end by the Spokane River. Originally occupied by the Coeur d'Alene Native Americans, a tribe of only a few thousand, the area provided a substantial subsistence for the tribe members, and the native wildlife and plants which flourished within the river basin for hundreds of years. Pristine water and fertile soil provided for the needs and nourishment of all the inhabitants who depended upon the life-giving water source. That is, until 1883, when railroad operators traded the life-giving capacity of the river basin environment for profits generated by railroad passengers.

To encourage more rail travel, and profits, the Northern Pacific Railroad advertised the discovery of gold within the Coeur d' Alene basin. One a dramatically altered, and some would argue irreversibly changed, the Coeur d' Alene basin and its life-giving capacity. Designated a heavily-contaminated Superfund site, this trade-off between environmental sustenance for profits proved detrimental.

3.3.5.1 EPA Superfund Designation

EPA developed processes to establish and identify Superfund sites. Metrics included physical site definition, human and ecologic risk assessment, remedial planning, and decision making. To determine EPA use and suitability of Superfund processes, Congress insisted EPA obtain independent NRC review of Superfund-identification practices and guidance, utilizing Coeur d' Alene as the case study.

The following sections summarize the history, background and controversy associated with Coeur d' Alene mining development and operations, and the subsequent NRC assessment regarding EPA Superfund practices and guidance. Historical details are germane to the context regarding contamination magnitude, including the recent metal-loading remediation plan developed by EPA under contract with URS Greiner and CH2M Hill.

Full details of Coeur d' Alene as a Superfund site are contained in the Coeur d' Alene NRC report (NRC, 2005). The history of Coeur d' Alene environmental damage, EPA Superfund designation, and the subsequent metal-loading remedial assessment process apply to research between assessment-based decision-making and stakeholder perceptions.

3.3.5.2 Coeur d' Alene History

Within a few months of advertising the availability of gold, an estimated 5000 gold prospectors and others looking for a short-term revenue source arrived in the river valley. The discovery of gold in these valleys led to the richer discovery of silver-lead-zinc ores along the tributaries and primary branch of the South Fork of the Coeur d' Alene River.

Beginning in May 1884, the first lead-silver mine was the Tiger, near what is now Burke, Idaho. Mining operations rapidly expanded along the richest and most productive seams in the area, leading to renaming the valley "Silver Valley". However, the ores were also rich in lead and zinc. Thus the original invitation to find gold via the railroad ultimately invited the high-dollar, high-waste, toxic mining methods necessary to extract silver, lead and zinc from the bedrock of the valley.

The mining operations soon expanded into milling operations to separate the valuable ore from the rock. These separators, or concentrators, were known as "jigs", utilizing processes involving crushing the ore until it resembled the size of coarse sand. Mixed with water, and passed across a grooved "jig table" or through a "jig cell", the larger, heavier pieces collected in the grooves in the bottom of the table, while the smaller, waste pieces were carried off the tail of the jig to become "jig tailings." Jig tailings were dumped into nearby streams. The tailing, including the mud and rock mixture, became known as "slimes".

The mine operators failed to realize the toxicity of the jig tailings and slimes, which contained high quantities of lead and other metals. These high-dollar, high-

waste processes, combined with the tight quarters of the river valley, led to conflict between the mine companies and the miners.

Some argue the technology did not exist at that time to understand the toxicity of the waste. However, by 1903, the waste was visible downstream, as were its detrimental effects on livestock and vegetation. Then, in 1929 and 1930, the editor of the Coeur d' Alene newspaper, John Coe, published the fact that Canada prohibited dumping mining waste into streams, and Canadian mine operators remained profitable (Aiken, 1994).

Technological advances in the mining process improved ore extraction and separation efficiency. Mine operators built wooden dams on the rivers and streams to hold the accumulating highly toxic waste. As efficiency increased, increasing mining production and waste dumping, the dams failed, sending the waste downstream into the lake.

Mining companies began smelting ore to increase local production efficiency. Groundwater, surface water, and air from the smelters became more infected. The toxic evidence appeared downstream in the Coeur d' Alene river basin. The atmospheric haze settled over the mining towns. The lake and river water turned into a murky, pungent sludge. Mine owners and operators fought against the mounting evidence, simply purchasing "smoke rights", in addition to citing their mining and dumping rights (Aiken, 1994; NRC, 2005).

The struggle between purveyors of toxicity against the public health interest remains historically pervasive throughout the 20th century and into this one. From multiple stakeholder perspectives, Coeur d' Alene history could be repeating itself

across the country currently with the advent of liquid natural gas pipeline developments and fracking operations. The question is: what have we learned from the Coeur d' Alene decision-making process and stakeholder perception management which we can apply today? The answer, according to this research is: Much.

3.3.5.3 Controversy

3.4 *Legal Controversy*

Also in 1991, two Natural Resources Damages (NRD) lawsuits were filed against the mining companies. The State of Idaho sued the mining companies for \$50 million, which was later settled for \$4.5 million.

The Coeur d' Alene Tribe filed another NRD suit against 8 mining companies, including ASARCO, the parent of Bunker Hill Mining. The United States joined the Coeur d' Alene tribe lawsuit in 1996. ASARCO paid the US government \$1.8B December 10, 2009 for environmental cleanup at contaminated mines in 19 states as part of a bankruptcy reorganization enabling Grupo Mexico to take control of ASARCO (Fifield, 2009).

3.5 *Environmental Controversy*

In 1983, EPA added the Bunker Hill Mining and Metallurgical Complex on the Coeur d' Alene river to the National Priority List (NPL) for Superfund sites. Throughout the 1980's and 1990's, subsequent reforestation efforts failed. In 1991 and 1992, EPA issued two Records of Decision covering cleanup of the Coeur d' Alene area (NRC, 2005).

In 2002, EPA issued a Record of Decision providing a "final remedy" of the entire project area contamination and risks to environmental and human health, at a cost of \$359 million over 30 years. Subsequently, under congressional direction, EPA asked NRC to independently review the Superfund technical designation process. NRC published the assessment of EPA Superfund designation processes in 2005, using Coeur d' Alene as a model (NRC, 2005).

The committee found substantial improvement areas for improvement, including questioning the applicability of the Superfund process to complex megasites such as Coeur d' Alene. Cleanup costs, geographic size and complex nature of contamination at Coeur d' Alene expand beyond a simplistic contamination remediation assessment process. Indeed, one committee member voiced significant concerns regarding the controversial risk assessment processes in an appendix.

3.6 EPA Risk Assessment Process Controversy

Edmund A. C. Crouch, Ph. D., describes issues with the probabilistic model for estimating metal loading and effectiveness of the remedial action in Appendix F of the Coeur d'Alene superfund document (NRC, 2005). Dr. Crouch specifically questions the PTM assumptions of variability and uncertainty distributions as lognormal distributions, specifically suggesting confusion within the assessment between uncertainty and time variation.

In addition to committee-documented shortcomings, Dr. Crouch found typographical errors in the analytical equations. He specifically articulates four deficiencies within the metal-loading remediation assessment: 1. The hypothesis is

untested; 2. Issues with the treatment of time variation; 3. Undocumented, nonreproducible, and un-validated parameters and their values; 4. Incorrect probabilistic analysis.

3.7 Risk Assessment and Risk Management Decisions

3.7.1 NBAF

3.7.1.1 EIS Initial Conditions

Complying with federal NEPA mandates, DHS delivered an EIS indicating Manhattan, Kansas as the preferred NBAF alternative (DHS, 2008). GAO evaluated the EIS, reporting DHS neglected addressing whether FMDv could be safely conducted on the mainland. GAO included economic impacts of an FMDv outbreak and whether an island affords additional protection from an outbreak in its report to Congress (GAO, 2008).

GAO found DHS based its assessment on a 2002 study which addressed the technical feasibility of conducting FMDv research on the mainland with appropriate safety procedures in place designed to protect the agriculture economic sector (GAO, 2008). These are different questions with different answers, suggesting simply because something is technically feasible does not mean it should be done (GAO, 2008).

Federal analysis of the EIS documented shortcomings relative to FMDv research (NRC, 2010; NRC, 2012; GAO, 2008; GAO, 2009).

NBAF initial EIS risk assessment identified eight hazards (DHS, 2008):

- Spill/Uncontrolled Release of Pathogens

- LAI
- Loss of Infected Animal/Insect
- Release of Contaminated Wastes
- Large Room or Facility Fire
- Over-Pressure Event from a Deflagration
- Seismic Event
- Aircraft Crash into the Facility

The initial risk management decisions contained within the EIS included site selection, operation and funding of the NBAF. The EIS evaluated six alternative sites regarding land use, infrastructure, air quality, noise, geology, water, biological and cultural resources, and socioeconomics, traffic, waste management, and health and safety, indicating Manhattan, KS as the preferred alternative. The EIS contained an assessment of the no action alternative, and overlooked hazards associated with pathogen release, specifically FMDv (DHS, 2008).

DHS indicated the EIS would assess whether FMDv research could be safely conducted on US mainland (Shea, Monke, & Gottron, 2008). However, the DHS ROD in January 2009 overlooked this assessment (Federal Register, 2009). As a result, Congress restricted construction funds until DHS delivered a risk assessment regarding whether FMDv research can be conducted safely on the US Mainland and GAO reviewed the assessment (GAO, 2009).

GAO analysis of the DHS EIS revealed multiple shortcomings regarding whether FMDv can be conducted on the mainland as on Plum Island (GAO, 2009). Congress mandated GAO analyze the NBAF EIS, finding shortcomings in FMDv release analysis, economic impact assessment and modeling (GAO, 2009). (GAO, 2009). GAO quantified health, economic and beef industry infrastructure hazards and impacts should FMDv research move to the U.S. mainland (GAO, 2009).

Table 3 contains the issues GAO found with the DHS EIS (GAO, 2009). GAO consulted with experts from multiple national laboratories, academic institutions, and consultants regarding the validity of the EIS assumptions, methods and modeling, and assessment processes. GAO found several deficiencies contributing to the underestimation of the overall risk associated with the capability of DHS to conduct FMDv research on the US mainland. As a result of the GAO findings, Congress again withheld construction funds. Congress mandated DHS conduct a site-specific risk analysis and submit it to NRC for independent review (NRC, 2010b).

<i>Deficiency Area</i>	<i>Identified Gaps</i>	<i>Comments</i>
Plume Modeling Limitations	Straight-line Gaussian plume model applies to PRA for nuclear radiological aerosol spread. This model lacks validation for FMDv spread.	Appropriate model developed for localized puff diffusion of low-frequency complex FMDv releases (RIMPUFF). Gaussian model lacks input accounting for biological decay rates.
	Meteorological data and source term assumptions introduced errors.	DHS submitted a year's worth of average weather data to the Gaussian plume model. More appropriate and reflective modeling would utilize actual data from each site. DHS underestimated the spill size, contributing to errors in the source term of the amount of amount of aerosol released.
	DHS failed to model of FMDv spread after infection.	Modeling FMDv spread depends upon the site, available vectors, local susceptible livestock and wildlife populations, and local agriculture economic market.
Economic Analysis Shortcomings	DHS concluded an export ban would result from an FMDv outbreak. Weaknesses include limited outbreak scenarios and missing details.	DHS failed to consider market response to an FMDv outbreak and associated costs of establishing a containment zone.
Plume and Economic Not integrated	EIS is missing integrated release scenarios with FMDv dispersion and spread relative to specific sites	Plume and dispersion assessment assumptions differ from the epidemiologic assessment

	and local impacts	assumptions to predict economic impacts. Missing connection regarding economic impact differences between Plum Island and mainland sites.
Little Site Differentiation	Little differentiation between sites regarding risks	EIS identified different factors at each site (<i>i.e.</i> proximity to livestock) the associated risks were considered inconsequential.
Large Animal	DHS overlooked hazards regarding working with large animals. Animal control listed as one of the risks.	Large infected animals reflect containment hazards. The risk was not quantified.

Table 3 GAO Concerns Regarding NBAF EIS

Subsequent sections elaborate regarding each EIS deficiency GAO documented (GAO, 2009).

3.8 EIS Gaussian Plume Modeling Deficiencies

Gaussian plume models lack input accounting for biological decay rates. The model assumes particles disperse in a Gaussian distribution, assuming a uniform wind and continuous release of a constant strength. According to GAO, DHS experts from Lawrence Livermore National Laboratories (LLNL) questioned using Gaussian plume modeling, indicating limitations within the Gaussian plume model actually applied to a viral release. Therefore, LLNL experts questioned applying a Gaussian plume model to an FMDv release, citing the lack of an established model appropriate for FMDv release tracking (GAO, 2009).

Conversely, experts from Johns Hopkins University Applied Physics Lab indicated the Gaussian model useful for aerosol release, citing model limitations regarding sufficiently and accurately describing effects associated with a specific release event. APL experts suggested limiting Gaussian plume model results as a

general estimation of a hypothetical release situation, instead of interpretation as a definitive result. MIT and the Department of Defense Threat Reduction Agency suggested the Hazard Prediction Assessment Capability (HPAC) model as a method to estimate long-range dispersion. This model, however, lacks validation for FMDv release, although the model accounts for variables regarding landscape and wind.

Danish experts suggested RIMPUFF for modeling FMDv release. This model is used in Europe for predicting accidental nuclear releases, chemical gas releases and specifically FMDv spread. RIMPUFF application aligns with assessment of FMDv release spread because the model uses parameterization, a technique common for modeling low-frequency complex problems. RIMPUFF considers wind, precipitation, and turbulence variables using scaling theory over multiple time scales. Further, this model considers biological decay of FMDv (GAO, 2009).

DHS contracted with Lawrence Livermore National Lab (LLNL) to review the EIS. LLNL indicated results of a Gaussian plume model as insufficient (GAO, 2009).

3.9 Meteorological data and source term assumptions

The Gaussian plume model defines atmospheric stability according to one of six possible categories. According to the experts GAO consulted, few atmospheric models use these six categories. Called Pasquill stability categories, more advanced models include additional atmospheric variables using more advanced tools. As a result, the Gaussian models remain location-dependent. DHS confirmed using weather data from locations other than the actual sites, thus contributing to questions regarding atmospheric dispersion modeling.

The five-factor source term contained an estimation regarding spill size. DHS estimated a small-to-medium-concentration spill from a gel-based agent. GAO consultation with experts in Denmark found higher actual concentrations of FMDv in stock solutions. Gel is rarely used. The particle size and decay rate were also underestimated, confirmed by APL analysis, suggesting the dry deposition removal rates were overestimated. APL research indicates FMDv particles are larger than 1 micron, which settle at significantly slower rates than DHS described in the EIS.

3.10 EIS Economic Impact Shortcomings

DHS conducted a literature review of FMDv outbreaks overseas, and requested BKC conduct a “quick and limited” economic analysis of FMDv outbreak at each site (GAO, 2009, p. 34). Recognizing limitations associated with quick analyses, BKC suggested DHS conduct additional economic analysis. The literature review lacked site-specific impacts, and according to DHS, was intended to bound economic losses instead of providing a comprehensive economic assessment at each site. OIE is the intergovernmental agency responsible for animal health worldwide, providing three possible FMDv classifications applicable to each country: present with or without vaccination, absent with vaccination or absent without vaccination. OIE also establishes the containment zone regarding specific surveillance, control and biosecurity measures for animals and specific diseases. The economic analysis neglected to include evaluation regarding the containment zone for each site.

The Biodefense Knowledge Center at LLNL (BKC) analysis did not assess the scenarios contained in the EIS or the plume modeling of those scenarios. Instead, the BKC analysis noted more advanced weather and dispersion modeling would be needed to quantify the relative risk rankings of each site. Recognizing limitations in its economic and epidemiological analyses, BKC recommended DHS conduct comprehensive assessments including consequences of accidental release at each site evaluating the location and quantity of susceptible animals; modeling with improved source term and regional meteorological data applicable to the EIS scenarios; and using more advanced dispersion models. BKC suggested modeling the eight EIS release scenarios at each would provide information useful for making siting decisions to DHS. BKC indicated analysis regarding estimating FMDv release leading to infection of at least one animal at one location would require an assessment by a “qualified risk analysis team” (GAO, 2009, p. 39).

3.11 Lack of Integration Resulted in Site Similarities

An effective risk assessment includes evaluation of FMDv release scenarios regarding site-specific infection and dispersion effects and impacts. Lack of comprehensive dispersion modeling of release scenarios integrated with site-specific epidemiologic and economic impacts blurred differences between Plum Island and mainland sites. The EIS assessed the release and dispersion associated with each site equally, neglecting to use similar assumptions for infection and epidemiologic modeling as used for the plume modeling. Similar assumptions led to similar results,

providing little difference between mainland sites. The EIS ranked Plum Island slightly safer than mainland sites based upon the island location.

3.11.1.1 Mandated Risk Assessment and Management Decisions

As a result of GAO's critical assessment of the NBAF EIS, Congress appropriated NBAF 2009 federal funding based upon delivery of an acceptable SSRA (111th Congress, 2009). Congress requested formal assessment of hazards associated with dispersion pathways and animal infection from FMDv release, the resulting economic impact, and an independent NRC assessment review (111th Congress, 2009). Congress defined the SSRA elements to contain (NRC, 2010b):

- a. Site-Specific biosafety and biosecurity risk assessment
- b. Integrated analysis using plume modeling and epidemiological impact modeling to assess the extent of the dispersion of the foot-and-mouth virus following a potential laboratory spill, the potential spread of foot-and-mouth disease in the surrounding susceptible animal population, and its economic impact;
- c. Requirements ensuring safe facility operation in Kansas
- d. Integrated analyses of specific local, State, and national risk mitigation strategies in the event of FMD release or another dangerous pathogen
- e. NRC Review of the SSRA

GAO and Congress commissioned the SSRA for two primary reasons: (1) because DHS failed to specifically address whether FMDv research can be conducted as safely on US mainland as PIADC and the EIS did not evaluate an FMDv release; and (2) DHS failed to commission a study showing FMDv research can be safely conducted on US mainland (GAO, 2009; GAO, 2008). According to DHS, motivations for the SSRA were "intended to assist DHS by providing input on design strategies, operational considerations, and mitigation and response planning at the

early stages of the facility development program.” (NBAF SSRA, page ES-1). DHS subsequently contracted with Signature Science, LLC, to develop a site-specific risk assessment (SSRA).

Congress and GAO wanted to understand the risks associated with FMDv research on the mainland, and whether the impacts of a release would be equivalent to a release on Plum Island. Congressional decisions revolved around FMDv research, release and impacts specific to the Kansas site. DHS decisions revolved around constructing a safe facility to prevent a release. The two decisions reflect different perspectives and priorities.

Signature Science completed the SSRA in June 2010 for NRC review (Signature Science LLC, 2010; NRC, 2010b). The SSRA modeled 13 different pathogen release scenarios along four different transport pathways: liquid, solid, fomite/vector/carrier, and air. The NRC committee commended DHS and Signature Science regarding assessment methods, facility design plans, and hazard mitigation strategies. The committee suggested improvements regarding appropriate models and general validity. Table 4 lists NRC findings regarding the SSRA.

2010 NRC Findings (NRC, 2010):
1. The SSRA lacks evidence to support the conclusion that the risk of release resulting in infection is very low relative to the risk of infection introduced from an external source.
2. The SSRA overlooks critical issues, both site-specific and non-site-specific, that could significantly elevate the risk of accidental release and spread of pathogens.

3. The SSRA has several methodological flaws related to dispersion modeling, tornado assessment, and epidemiological modeling. Thus the committee believes that questions remain about the validity of the overall risk estimates.
4. The committee agrees with the SSRA's conclusion that for FMD virus, long-distance plume transport will likely be less important than the near-site exposure of cattle.
5. Substantial gaps in knowledge make predicting the course of an FMD outbreak very difficult, which led to weaknesses in the SSRA.
6. Although the economic modeling was conducted with appropriate methods, the epidemiological estimates used as inputs to the SSRA were flawed.
7. The committee agrees with the SSRA's conclusion that early detection and rapid response can limit the impact of an FMD virus release from the NBAF, but is concerned that the SSRA does not describe how the NBAF could rapidly detect such a release.
8. The SSRA lacks a comprehensive mitigation strategy developed with stakeholder input for addressing major issues related to a pathogen release. The mitigation strategies that are provided do not realistically demonstrate current or foreseen capacity for how federal, state, and local authorities would effectively respond to and control a pathogen release.
9. The committee agrees with the SSRA's conclusion that human error will be the most likely cause of an accidental pathogen release, and fomite carriage is the most likely way that a pathogen would escape the facility's outer biocontainment and biosecurity envelope.
10. The committee agrees with the SSRA's conclusion that investment in biosafety and biosecurity engineering and the training of personnel and responders can reduce the risks, but is concerned about current design plans that potentially compromise safety measures.

Table 4 NRC SSRA Deficiencies and Findings

Conversely, the committee found critical technical shortcomings of the SSRA, including failure to address congressional and GAO concerns regarding the safety of conducting FMDv research on the U.S. mainland (GAO, 2006; GAO, 2009; Dourson & Patterson, 2003; NRC, 2010b). The committee indicated model inputs and assumptions neglected to account for operational activities associated with BSL-3 and BSL-4 labs. The committee further noted assessment gaps regarding how pathogens

might be released, and the resulting potential exposed animal populations. Identified shortcomings suggested an underestimation of the specific risks associated with an FMDv release in the economic center of the beef industry.

Citing pathogen release as a “generic” risk, the reviewers indicated health and economic impacts of a release depend upon the NBAF location, suggesting DHS underestimated the potential negative economic impacts with locating the NBAF in Kansas (NRC, 2010b, p. 2). In addition to the NRC, other stakeholders including GAO, Congress, and concerned citizens, suggested DHS improve its assessment of FMDv release impacts in Manhattan (GAO, 2009; 111th Congress, 2009; Concerned Citizens, 2008).

3.12 Stakeholder Engagement Plan

The SSRA contains twelve appendices including Appendix A Stakeholder Engagement Plan (DHS, 2010). DHS recognized stakeholders’ need regarding design, construction, commissioning, and operational information. Engagement plan objectives included:

- Identification of activities to inform and engage stakeholders;
- Dialogue facilitation among DHS, USDA and stakeholders to establish public confidence;
- Develop communication channels for the dialogue, including a Stakeholder Engagement Committee;
- Engage the Manhattan, KS, local community to earn public trust;
- Outline NBAF preliminary risk communication strategies.

The plan identified the lead agency (DHS) and the stakeholders, with specific engagement activities aligned to different stakeholders. Table 5 NBAF Stakeholders and Engagement Activities lists the defined stakeholders and activities associated

with each group. The activities were designed to develop dialogue between DHS and each group, with the goal of increasing public confidence in the NBAF and its operations.

<i>Identified Stakeholder</i>	<i>Engagement Activities</i>
Local Community (Manhattan; Kansas State University; and Heartland BioAgro Consortium (HBAC))	NBAF to conduct open houses, facility tours, and town halls so the public can learn about laboratory operations and the control measures in place; establish a Stakeholder Engagement Committee (SEC).
Private sector; non-profit and non-governmental organizations; academia	Establish research forums, national conferences and general meetings for these groups; meet monthly with HBAC; maintain a public web-based calendar of meetings and events.
DHS, USDA and other Federal agencies	Provide agencies updates via materials, website updates, meetings and briefings, including meeting with PIADC leaders.
State and local government	Same as above
Congress	Inform Congress via legislative affairs channels, and specifically via Office of the Under Secretary for S&T, the Office of Strategy, Policy and Budget, the Office of Legislative Affairs, and the Office of Public Affairs to conduct briefings, answer questions, and receive feedback from members of congress and their staff
General Public	Same as above

Table 5 NBAF Stakeholders and Engagement Activities

Research on the NBAF website and academic sites resulted in little information regarding the suggested plans. Members of the SEC remain unknown. HBAC offers little information. The largest purveyor of information supporting the NBAF is the NBAF in Kansas website, established by the Kansas governor's office.

3.12.1.1 Updated Site-Specific Risk Analysis (uSSRA)

Congress continued withholding construction funds. In 2012 NRC reviewed the congressionally mandated updated SSRA (uSSRA) (NRC 2012). Although improved, this committee found the uSSRA underestimated risks associated with pathogen release and infection, including incomplete uncertainty characterization. For example, the uSSRA reduced FMDv release probability to 0.11% from an original estimation of 70% during the 50-year NBAF lifespan. The committee questioned assumptions within the uSSRA, suggesting invalid assumptions led to “artificially lower probabilities and amounts of pathogens released” (NRC, 2012, p. 2).

Despite improvements, the 2012 NRC committee found the uSSRA incomplete in application, modeling, and an underestimation of pathogen release (NRC, 2012). NRC findings regarding the uSSRA are listed in Table 6 NRC Findings of uSSRA. DHS again missed conducting a risk assessment regarding FMDv release, indicating weather or seismic activity the most likely source pathways of a release (NRC, 2012). The original SSRA indicated fomites or lack of personal respiratory protection as the likely source. Conversely, both risk assessment reviews contain overlapping recommendations and criticisms:

1. Ignoring probabilistic dependencies within risk scenarios, possibly leading to an underestimation of the risk of FMDv release
2. Incomplete and inconsistent application of risk methods with respect to the scenario based modeling in the uSSRA, specifically tornado assessment and epidemiological modeling.
3. Inconsistent application of scenario-based modeling.

NRC Findings Regarding uSSRA (NRC, 2012)
1. uSSRA does not adequately include the overall risks for the most dangerous pathogens
2. 65% design phase documents APPEAR sound, but were not studied in detail.
3. uSSRA misinterprets and misapplies some risk methods; inconsistent application of “scenario-based” risk analysis approach.
4. uSSRA ignores probabilistic dependencies in risk scenarios; could possibly result in underestimation of accidental FMD release
5. Incomplete and inconsistent characterization and assessment of uncertainties
6. uSSRA assumes low human error rates, and omits error pathways, without justification of the reason NBAF workers are less likely to make mistakes than similar workers in similar facilities
7. uSSRA uses overly optimistic values in the models, yet describes those values as conservative (the presence of biases contributes to shifting results by orders of magnitude)
8. Lack of approach descriptions, illustrated by a less-than thorough literature review of risk assessment assumptions, illustrated by usage of outdated or single references.
9. Modeling improved, with gaps in model limitations and model data, leading to uncertain results and conclusions, particularly with regards to an underestimation of the spread and duration of an FMD outbreak.
10. Economic analysis of FMD outbreak lacks reproducibility of the results and an inability to assess the execution of the economic analysis. Carryover of Finding 9 into the economic analysis gaps in Finding 10.
11. Committee questions the uSSRA conclusion of greatest hazard posed by natural disasters. Committee also found an overestimate of the probability of natural disaster occurrence. Committee found that risk assessments of an FMD release due to earthquakes and tornado are too high.
12. uSSRA relied upon incomplete, science-based assumptions regarding surveillance, detection, response and mitigation strategies with insufficient input from all government stakeholders at the local, state, and federal levels. For example, vaccine availability strategies are incomplete or completely lacking, yet are critical for managing an FMD outbreak. This is a duplicate of Finding 7 from 2010 NRC evaluation of the original SSRA. DHS and USDA continue to lack the plans, programs and strategies to manage an FMD outbreak.
13. Committee found lack of preparation and training regarding security, lab procedures & processes, and emergency response at NBAF, as required by P.L. 112-10. DHS needs to fully address and document these processes and training.
14. In the BSL-4 assessment, the uSSRA lacks an overall risk assessment as well as a qualitative impact assessment. The risks presented focus on the unique risks associated with the use of large animals, which limits the overall risk assessment of operating a BSL-4 laboratory.

Table 6 NRC Findings of uSSRA

3.13 Updated Stakeholder Engagement Plan

Objectives and stakeholders of the plan remain unchanged from the original SSRA (DHS, 2012). The specific members of the referenced Stakeholder Engagement Committee remain undefined (State of Kansas, 2009).

On July 15, 2011, however, the Kansas governor's office established the "NBAF in Kansas Steering Committee", whose members are primarily elected political officials. Kansas Board of Regents Chair Tim Emert, and Kansas State University President Kirk Schulz, are notable exceptions. The appointment of these two gentlemen reflects the political process, in that governors appoint members onto Boards of Regents and Regents select postsecondary institution presidents.

3.13.1.1 Risk Analysis in DHS

In 2008, at congressional request, NRC appointed a committee to review risk analysis within the agency (NRC, 2010c). The committee provided insight regarding improving risk-informed decision-making across the agency (NRC 2010c). The committee suggested ten areas for improvement within DHS. Note the timing of the assessment of DHS expertise occurred during the NBAF risk assessment process.

Findings:

1. DHS should improve its scientific analysis practices, including documentation, validation and expert peer review, and also improve its internal risk analysis skillset.
2. DHS should develop longer-term analysis capabilities for natural hazard risk assessment, including the development and quantification of uncertainty.
3. DHS should include models which allow adaptation to changing observed conditions, such as Bayesian models, game theory, and other research-based models.
4. DHS needs to insure that risk analyses are documented, transparent and repeatable (i.e. TCCR per EPA 2000). Maximize transparency.

5. Develop a comprehensive risk communication plan and strategy for all stakeholders.
6. Comprehensive, single integrated risk analysis is untenable for an agency with a wide variance of risks to study, understand, articulate and manage. Comparative risk assessment is a better approach for each situation.
7. Include both qualitative and quantitative assessments, moving away from singular quantitative numbers, given the complexity of assessment and threats under DHS purview.
8. DHS should develop a risk assessment lexicon.
9. Develop and document models, subject those models and methods to peer review, and improve, including sensitivity analysis.
10. DHS should improve and expand the risk analysis team of experts internal to the agency.

The Biodefense Knowledge Center (BKC) at LLNL suggested using a competent risk analysis team to assess hazards and impacts associated with FMDv release at a specific NBAF site (GAO, 2009). Johns Hopkins, MIT and LLNL found inconsistent modeling application and model input assumptions in the NBAF risk assessment (GAO, 2008; GAO, 2009). A critical NRC review regarding DHS risk analysis skills documented similar shortcomings, inconsistencies and risk assessment skills gaps within the agency (NRC, 2010c).

Independent NRC review validated stakeholder concerns regarding NBAF risk assessment shortcomings. In 2010 the NRC documented 11 improvement recommendations regarding the SSRA. DHS conducted an updated SSRA, and two years later another NRC committee duplicated eight of the original 11 recommendations in 2010 (NRC, 2010b; NRC, 2012). Connecting the duplicity between NBAF risk assessments, DHS received a critical review regarding risk assessment skills within the agency (NRC, 2008b; NRC, 2010c).

3.13.2 NEIDL

The initial conditions considered within this analysis originate in 2008, when NIH complied with court orders by contracting with Tetra Tech, Inc. to conduct the risk assessment, incorporate public and NRC comments, and include BRP feedback.

3.13.2.1 Initial Conditions

Initial conditions regarding the NEIDL risk assessment hazards and decisions originate from the April 2008 BRP input to the risk assessment scope and process with the NRC review committee (NRC, 2008d). Initial conditions associated with the new supplemental risk assessment include a comprehensive assessment of pathogens, release scenarios, and communication with stakeholders regarding the probability associated with NEIDL operational hazards.

Beginning with the inadequate DSRASSA, the NRC recommended risk assessment scope and approach improvements (NRC, 2008d). Three overarching questions summarize initial conditions regarding NRC approach to risk assessment and decisions associated with operating the NEIDL in South Boston:

1. What could go wrong? (*i.e.* release scenarios and pathogens to include into the risk assessment)
2. What are the probabilities of such an event sequence?
3. What would be the consequences?

These questions formed the risk assessment framework. The NRC committee recommended a two-phase analysis, suggesting an initial phase containing an analysis based upon reasonable scenarios comparing three alternative sites, and including an analysis of a low-frequency, high-impact event. Following the initial analysis, the NRC suggest phase two encompass a comprehensive analysis of pathogens,

transmission pathways (blood, fomites, vectors, aerosol), and addressing equipment failures, malevolent actions and workplace procedural failures.

The NRC suggested the comprehensive analysis include probabilities associated with each transmission method and four transmission scenarios: small initial infection pool, with no transmission; multiple exposure pool, with small transmission; public health measure to contain a multiple exposure pool, with small transmission; and large transmission (NRC, 2008d). Additionally, the NRC recommended a qualitative analysis of the local characteristics (population, public health infrastructure, vector availability, etc.) on the probability of the four transmission scenarios. The NRC also recognized critical implications regarding risk communication, suggesting NIH employ validated communication methods from the literature, and comply with EPA TCCR principles, clearly articulate and substantiate defaults, including communicating uncertainty and sensitivity analysis (EPA, 2000; NRC, 2008d).

With NRC suggestions as a framework, NIH contracted with Tetra Tech, Inc. to deliver a risk assessment which would withstand court scrutiny (NIH, 2008). The assessment compared four alternative sites; expanded list of pathogens and exposure pathways; assessed potential infection spread; identified preventative safety and security controls; and identified response strategies should escape occur (NIH, 2008).

3.13.2.2 Updated Assessment; Updated Decisions

3.14 Phase I

The NRC committee reviewed the Phase I NEIDL risk assessment and provided feedback to NIH in April 2010. According to the NRC committee, Phase I consisted of plans and approaches, with results forthcoming (NRC, 2010). The NRC committee found the range of agents, event sequence analysis, and modeling approach appropriate. The committee advised NIH adhere to TCCR principles in risk analysis and communication, allowing input from all stakeholders (EPA 2000). The committee cautioned against using extreme value analysis, instead suggesting emphasis on low-frequency, high-impact scenarios and associated sensitivity analysis, including expert judgment (NRC, 2010).

3.15 Phase II

In Phase 2, the NRC committee noted shortcomings in the risk assessment. The original three questions remained unaddressed. In the Phase I analysis, the committee suggested a qualitative to quantitative approach to including expert subjective information.

The assessment lacked transparency, uncertainty analysis, and default justification. The committee criticized NIH and Tetra Tech for avoiding a tiered qualitative and quantitative approach to address the Phase I original three questions for 13 pathogens. The committee suggested an iterative analysis to obtain direct scientific data and indirect scientific expert judgment as evidence into the model, a

process outlined in the updated Red Book risk assessment process (NRC, 2010a; NRC, 2008).

The committee criticized NIH for using a modified Delphi process to obtain input on several unknowns associated with the 13 pathogens, averaged over three infectious doses fitted to three plume/puff exposure models dependent upon expert opinions. The committee indicated fitting opinion to quantitative modeling is unnecessary, potentially leading to misleading and possibly invalid results (NRC, 2010a).

3.16 Phase III

The Phase 3 review occurred at the 90% complete stage of the NEIDL risk assessment. The 90% complete risk assessment contained prior NRC committee recommendations, resulting in a complex, comprehensive assessment. The updated assessment and decisions reflected risk assessment practice, quantification, and communication, including NRC critical feedback, public comments, and BRP suggestions.

Reflecting risk communication methodologies, the NRC Phase 3 comments offered five general improvements associated with the assessment and its presentation to the community: inclusion of an Executive Summary and risk assessment summary written in plain language; documentation of a safety culture at BU and the NEIDL; justification regarding omission of a “carry-out” scenario, where a pathogen could be unknowingly carried out of NEIDL on a worker’s clothes; differentiation between conclusions based upon expert opinion and those based upon data; inclusion

of cross-referencing to reduce navigation complexity through the document (NRC, 2011b).

The NEIDL decisions throughout the risk assessment process reflected compliance with court orders regarding technical and communication improvements (NRC, 2010; NRC, 2010a; NRC, 2011b). At the turn of 2007 into 2008, NIH recognized the value outside stakeholders brought to the risk assessment process. NIH decisions demonstrated evidence of this recognition. NIH involved incorporating NRC recommendations, expanding the risk assessment methodology, developing a comprehensive feedback process including all stakeholders, and expanding community involvement.

3.16.1 *Fort Detrick*

3.16.1.1 Initial Conditions

In 2010, the NRC independent review committee found the initial Fort Detrick USAMRIID EIS lacking. The risk analysis was incomplete; the risk characterization was insufficient including epidemiologic characteristics, route exposure and evaluation of alternative sites (NRC, 2010). The committee indicated the USAMRIID EIS lacked transparency regarding the development of the risk assessment, including failure to appropriately model potential possible transmission from a laboratory worker into the community. Further, according to the NRC review committee, the review was congressionally mandated based upon local community opposition. Yet the ROD had already been issued when the review occurred, documenting prior LAIs and lack of transparency to the community stakeholders.

Recognizing these deficiencies, the Army requested assistance from the same NRC in addressing these issues for the MCMT&E facility. The Army looked to the NRC for guidance to develop the risk assessment work plan for the MCMT&E high-containment laboratory facility. The NRC committee suggested the Army develop a detailed risk assessment protocol for the Ft. Detrick expansion, as well as any other future expansion (NRC, 2010d). The NRC committee was acutely aware of prior LAIs and subsequent public sensitivity throughout the community the LAI record raised. Therefore, the NRC strongly encouraged the Army to include community stakeholders and use the 2008 updated Red Book process (NRC, 2011). Although the location had been decided, the initial conditions regarding the risk assessment process lacked public stakeholder concern. Based upon critical feedback regarding USAMRIID, initial decisions at Fort Detrick involved the Army's implementation of NRC recommendations regarding risk assessment practice, transparency, and proven methodologies (NRC, 2011).

3.16.1.2 Updated Assessment; Updated Decisions

Facility design and staff training are critical components of risk mitigation within high-containment biosafety laboratories. The Army revised the MCMT&E EIS, deciding to expand the current facilities instead of constructing a new facility (NRC, 2011). The NRC letter report outlined the gaps in the work plan for assessing the risks associated with the facility. Noting misalignment between the risk analysis and the facility development, the committee strongly advised against conducting a risk assessment without facility plans available (NRC, 2011c). The committee

specifically articulated using the iterative 2008 risk assessment model to improve the MCMT&E risk assessment work plan, and ultimately the EIS (NRC, 2011).

Upon second review, published five months later in September 2011, the NRC committee noted the contractor who prepared the MCMT&E EIS viewed the risk assessment process as a chore, and hurdle to overcome, instead of as a collaborative, iterative effort with the local community (NRC, 2011c). The NRC committee criticized federal agencies, including the Army, regarding the lack of a consistent risk assessment framework across federal agencies, contributing to the MCMT&E insufficient risk assessment work plan. The 2008 NRC risk assessment model articulates developing a plan to conduct risk assessments, and iterating the hazards and mitigation strategies (NRC, 2008). The NRC recommended this process for the MDMT&E facility at Fort Detrick (NRC, 2011).

3.16.2 *IPET*

3.16.2.1 Initial Conditions

The US Army Corps of Engineers commissioned the Interagency Performance Evaluation Task Force (IPET) to conduct an engineering investigation to understand the root causes of what happened during Katrina, with the goal to apply lessons learned to the rebuilding of levees and other damage-reduction structures in and around New Orleans. In addition to developing and applying risk assessment practices to understand the risks from hurricane-induced flooding, the Corps of Engineers also requested the IPET team estimate risk after the new 100-year

hurricane storm damage reduction system (HSDRRS) is complete, in approximately June 2007.

IPET categorized hurricane protection system risk assessment within ten study topics over five general areas: a) the flood protection system; b) the storm; c) protection system performance; d) damage consequences; and e) risks to the New Orleans area from future storms & hurricanes (NRC, 2006). IPET planned to conduct NRC reviews at the 30%, 60% and 90% completion points of the risk assessment (NRC, 2006).

The IPET risk assessment revolve around IPET developing three primary topics: a) hurricane protection system design capacity; b) hurricane forces during the storm and the system's response; and c) overtopping, breaching, or failure causes of levees and floodwalls (NRC, 2006). The initial conditions of the risk assessment overlooked including risk communication methods or processes, elements which became increasingly critical as the IPET team progressed.

Initial conditions comprise NRC improvement suggestions based upon review at the IPET 30% completion point, captured in a 2006 letter report (NRC, 2006). The identified improvement areas involved system-wide and interdisciplinary issues; geotechnical data and investigations; and hydrology, hydrolics, and hurricane surge and wave analysis (NRC, 2006).

NRC identified specific technical gaps in the initial risk assessment. Intended to assess the protection system, the 30% risk assessment lacked a system-wide perspective. The NRC provided ten suggestions in its critique of the initial risk

assessment, listed in Table 7 NRC Recommendations of 30% Complete Risk Assessment.

NRC Committee Recommendations – 70% Complete Risk Assessment
1. Use GIS to facilitate analysis, understanding and communication.
2. IPET should include uncertainty in the assessment.
3. Geodesics should be used to connect the comprehensive assessment to the risk assessment purpose.
4. June 1, 2006 delivery date of a comprehensive risk assessment is too aggressive.
5. Establish the connection between IPET activities and overall system recovery.
6. IPET should increase technical assessment regarding soil and geologic data to enable root cause analysis.
7. IPET should increase technical assessment regarding levee foundation data to enable root cause analysis.
8. IPET should develop a region-wide geologic and soil map.
9. Define concepts “authorized level of protection” and “standard project hurricane” (SPH)
10. Input data accuracy and parameters need clarification, such that the modeling of future hurricane impacts contains a comprehensive approach.

Table 7 NRC Recommendations of 30% Complete Risk Assessment

3.17 System-Wide Perspective Gaps

Flooding maps lacked evidence of employing GIS technology, suggesting using GIS for analysis, visualization, and communication. The technology was available, and NRC considered it should be used to help inform the general public and visualize the area as a complete, comprehensive protection system.

Data collection and accuracy lacked uncertainty quantification and explanation. The committee suggested IPET characterize the level of confidence it had in the data gathered, including uncertainty estimates. The NRC suggested including explanations regarding relative data accuracy across the protection system, including reliability, for public understanding.

The assessment lacked comprehensive maps supporting the geodetic efforts IPET expended. The reviewers suggested connecting clear, comprehensive data to the protection system maps.

USACE requested report completion in June 2006, thus condensing the IPET team efforts into nine months. Reviewers noted compressing a schedule prevents thoughtful complete analysis, lending instead to hasty decisions with little room for correction when new information surfaces. Thus the logic associated with accelerating the report delivery schedule and providing system-wide recovery implementations remained unclear to the reviewers (NRC, 2006).

3.18 Geotechnical Data

The committee suggesting improving the description and analysis of system-wide geologic conditions across the Gulf region. The reviewers suggested describing the system-wide geologic conditions comprehensively to facilitate stakeholder understanding the distinction of failures. Some failures might be due to hydraulic loading, structural design, or foundation conditions. Such a geologic description served the stakeholders to understand the different geologic root causes, and whether similar conditions exist elsewhere in the levee system.

The committee noted this type of descriptive, separate knowledge as crucial in improving overall system preparedness and performance. Committee discussions with IPET team members suggested IPET was developing and presenting an overall regional geologic picture to support stakeholder understanding.

The 30%-complete risk assessment provided little information regarding system-wide and site-specific data collection and application. Data collected contained gaps regarding levee strengths and weaknesses, along with the underlying ground conditions, particularly at the 17th Street and London Avenue canal breaches. Missing the opportunity to suggest root causes of these particular disastrous breaches contributed to stakeholder skepticism (NRC, 2006). Further, the 30% report lacked the establishment of levee performance baseline via a site investigation plan. The reviewers suggested a system-wide plan instead of a forensic plan at the specific breach locations (NRC, 2006).

3.19 Hydrology and Hydraulics

Hurricane protection system design accounts for storm surge and waves associated with an appropriate level of preparedness. The design questions include the limits of the storm surge and waves relative to a storm exceeding design parameters, or possibly a lack of maintenance, or both. The committee found inconsistent definitions in the 30%-complete risk assessment regarding establishment of an authorized protection level; defining a standard hurricane; water level heights on a frequency; and flooding probability. The IPET report emphasized wave and surge models, without detailing relative interactions of the models, including associated parameter and model uncertainty. The reviewers suggested IPET provide these details in subsequent risk assessments (NRC, 2006).

The initial conditions associated with IPET include references to the 2008 updated Red Book risk assessment process, although IPET was conducted two years

prior. The committee suggested planning the risk assessment prior to conducting the risk assessment, including verification of stakeholder goals and values at the outset, particularly when solving volatile problems.

“When a large, comprehensive field study of the scope of the IPET investigation is undertaken, it is vital to carefully specify during the initial planning stages what data are to be collected, how they are to be collected, and how they are to be presented, and to list the analysis to be conducted. *Doing so in a study’s early stages is even more important when several entities are involved in the study. In the case of the IPET studies, all tasks to be pursued should be planned to fit into and support the goal of the parent study, which should ultimately enable the design of a hurricane protection system to adequately protect New Orleans.* In a politically charged study such as this one, it is tempting to get into the field immediately in order to show that something is being done. Unfortunately, if a clear, definitive, and system-wide approach is not established at the beginning, the ultimate results may well turn out to be less than desired.” (NRC, 2006, p. 11). (Emphasis added).

3.19.1.1 Updated Assessment; Updated Decisions

3.20 70% Complete Risk Assessment and Second Review

Subsequent NRC reviews represent updated risk assessments and decisions associated with the New Orleans and vicinity hurricane protection system. The 70% report serves as the second review of the risk assessment.

In the 70% review, the history changed from a 50-year complex management system into a 100-year management system, thus pointing to the complexity of the IPET team regarding balancing root-cause analysis and future preparedness (NRC, 2006b). The IPET team collected enormous amounts of data and technical information. The NRC reviewers reduced the effort to a data report, suggesting IPET improve integration between the data and report clarity.

Similar to the initial conditions, the committee suggested system-wide evaluations, including simple explanations of levee overtopping and levee breaches to enable stakeholder comprehension. Also similar to the initial conditions, the report lacked explanation regarding the policy-associated decision of an authorized protection level, and also lacked the definition of a standard hurricane (NRC, 2006b).

Other recommendations echoed the 30% initial conditions, including additional GIS maps as a framework for system-wide integration. The investigation into the 17th Street Canal breach and soil analysis seemed disconnected from the system-wide review (NRC, 2006b). The reviewers cited twelve recommendations, similar to recommendations in the 30%-complete risk assessment review.

The committee's second report indicated shortcomings with respect to providing credible engineering-based findings on a compressed schedule. The reviewers noted the decision to issue a draft final report in June 2006, instead of a final report, enabled IPET to improve credibility of engineering-based findings. IPET needed additional time for delivering a complete, comprehensive the final report serving the New Orleans area as a baseline to improve hurricane preparedness (NRC, 2006b). Table 8 NRC Recommendations of the 70% Complete Risk Assessment lists the twelve recommendations NRC identified in the second review. Discussion of each recommendation, including NRC specific details and suggested improvements, follows. The discussion regarding communication and use of an RPM occurs in chapters four and five.

1. Schedule delay improves comprehensive analysis
2. Repairs mask underlying vulnerabilities
3. GIS usage expanded as a framework to enable communication regarding system-wide risk
4. Define concepts “authorized level of protection” and “standard project hurricane” (SPH)
5. More data and analysis needed for IPET to deliver system-wide geotechnical assessment of the hurricane protection system
6. Assessment emphasis on the protection areas loaded to capacity without failing
7. Failure of 17 th Street Canal breach remains plausible. To insure validation, IPET should study other plausible root causes.
8. Direct-simple-shear (DSS) and field-vane-shear (FVS) tests should be conducted at 17 th Street Canal breach, and results integrated with an NSF-sponsored study.
9. IPET should compile a historical record of significant storms in the Gulf, with the SPH, as an element of the probabilistic analysis.
10. IPET should include comprehensive, understandable explanation of the risk and reliability methods used, including validation of probabilities assigned to protection system components, and clear uncertainty explanation.
11. IPET should include two separate estimates of hurricane wave levels at various locations across the system.
12. Expectations of a complete report by June 1, 2006 are too aggressive.

Table 8 NRC Recommendations of the 70% Complete Risk Assessment

The committee noted repair progress to the protection system damaged areas potentially masking broader risks across the system. IPET explained to the committee the levee breach investigations led to critical root-case failure modes which were outside design considerations of the New Orleans levees. The coastal geography near the Gulf and Mississippi River, coupled with low topography, increases storm surge and flooding vulnerability in New Orleans and surrounding areas. Coupled with growth, urbanization and wetland erosion, the committee suggested formal recognition regarding continuous vulnerabilities to provide broader awareness of risk to the general public in the final risk assessment (NRC, 2006b).

New Orleans residents should increase vigilance and awareness of vulnerabilities to their community.

Similar to the 30% report, the committee noted IPET should apply GIS as a framework for the risk assessment. The committee further suggested IPET establish a website for public review of GIS-developed soil maps, levees, and other critical components of the hurricane protection system. Specifically, the committee recommended public access to system-wide defined authorized levels of protection, existing levels of protection, and realistic worst-case surge and wave conditions (NRC, 2006b).

IPET again neglected to define the authorized protection level and also the standard project hurricane, similar to 30% assessment review. The NRC committee again suggested defining these terms to facilitate understanding and comprehension of the risk assessment. The committee also recommended connecting these concepts to levee design and protection levels prior to and also after Katrina (NRC, 2006b).

The NRC noted the magnitude of data and analysis remaining for IPET to deliver a comprehensive hurricane protection system geotechnical analysis. The NRC suggested IPET consider the intersection between levee construction history and regional geologic features. The various levee construction methods, resources, locations and maintenance provide opportunities evaluate hurricane impacts. Coupled with geologic constraints and features surrounding levees, IPET should take advantage of the study opportunity to collect extensive data and conduct in-depth analysis (NRC, 2006b).

The reviewers suggested IPET assess areas of the protection system which Katrina loaded, yet held, as a component of understanding system protection levels. The reviewers connected the idea of hydraulic loading, without levee failure, to heightened system evaluation and public risk awareness, to enable stakeholder understanding regarding the overall system risks and stakeholder choices to remain or evacuate (NRC, 2006b).

IPET appropriately determined formation of a vertical gap in the 17th Street Canal levee I-wall between the concrete wall and adjacent soil on the canal side, indicating loading and deformation as a valid failure process. The NRC reviewers criticized IPET for failing to fully consider alternate failure mechanisms associated with the gap development. The committee identified IPET analysis limitations including full explanation regarding the gap between the soil and the levee wall on the canal side; Rensselaer Polytechnic Institute modeling of a similar failure mechanism which behaved differently than the behavior suggested by IPET using this model; and IPET rationalization between storm surge observations and timing predictions using models. Specifically, with respect to the storm surge observed and predicted modeling, the reviewers noted inconsistent application of applicable datums (NRC, 2006b).

The NRC suggested the case presented by IPET offering a root cause for the 17th Street Canal breach was unconvincing, offering additional suggestions to include uncertainty analysis into the failure probability assessment beyond averaging over multiple levee locations. The committee suggested direct-simple-shear (DSS) and field-vane-shear (FVS) tests at the 17th Street Canal breach site, and integrating the

results into previously acquired strength data. The committee strongly suggested IPET assess instability at multiple locations in the protection system, providing stakeholders with an overview of system stability.

Reviewers criticized IPET for using the concept of a standard project hurricane (SPH), and omitting the definition. The reviewers suggested IPET develop a probabilistic history of hurricanes in the Gulf of Mexico, categorizing major storms (e.g., Betsy, Camille, and Katrina), relative to the SPH to facilitate public understanding of the risk based upon choosing to live in the area.

Development of public risk perception and understanding of the system as a whole, the committee recommended IPET provide explanation for the method used in its assessment of risk and reliability of the hurricane protection system. IPET evidence should validate probabilities assigned to the various parts of the system. The explanation should also contain clear discussion identifying level(s) of uncertainty associated with these results.

The NRC suggested a two steps regarding hurricane wave estimations. Considering wave levels at various locations, IPET should analyze wave heights based on a relatively small set (e.g., ~50) of representative storms that include a worst-case scenario. The second suggested step involved joint probability analyses for a given storm along with the probability of occurrence of specific system failure modes.

Noting the aggressive schedule NRC suggested delaying the risk assessment to insure credibility.

3.21 90% Complete Risk Assessment and Third Review

The review committee met with IPET team members regarding the 90% complete risk assessment. The 90% risk assessment contained an Executive Summary, which earlier versions lacked. The Executive Summary contained twenty overall recommendations (NRC, 2006c). The list of recommendations is included in Table 9. The 90% review contained eleven recommendations contained in prior review reports, noted in the table as “repeated”.

NRC Committee Recommendations – 90% Complete Risk Assessment
1. Remove "negligence" and "malfeasance" from Executive Summary.
2. Develop consistency between Executive Summary and report body.
3. Align Executive Summary with the five overarching objectives of the IPET analysis.
4. Discuss improving the overall hurricane protection system in Executive Summary, beyond specific breaches. (repeated)
5. Add GIS maps illuminating hurricane protection system strengths and weaknesses in Executive Summary. (repeated)
6. Expand Executive Summary uncertainty discussion regarding future protection system planning and decisions.
7. Provide additional evidence regarding the IHNC breach root cause regarding overtopping and erosion, and the logic for limiting the root cause to these reasons. (Repeated, except for location)
8. Include shear strength of the marsh and clay deposits in the soil analysis, and soil field data at levee failure sites. (repeated)
9. Include soil profiles at the breach sites. (repeated)
10. Include marsh and clay strength analysis at levee locations in addition to the 17 th Street Canal. (repeated)
11. Include other possible failure modes, in addition to gap development between soil and levee. (repeated)
12. Include property and human values in the levee protection design safety factor.
13. Show erosion and its mitigation methods.
14. Include uncertainty estimation in the assessment. (Repeated)
15. Describe each variable and its associated uncertainty. (repeated)
16. Provide risk and probability of the standard project hurricane. (repeated)
17. Describe system risk in terms of overall protection, surge levels and other storm parameters to benefit stakeholders. (repeated)

18. Develop storm scenarios aligned with joint probability discussion.
19. Assess reliability of the present system design in terms of the Standard Project Hurricane.
20. Coordinate the assessment with other agencies.

Table 9 NRC Recommendations of the 90% Risk Assessment

Implications regarding the 90% risk assessment and its review germane to this discussion revolve around the repeated recommendations, and suggested improvements to aid decision-making and protection system planning. The 90% review provided suggestions designed to increase risk assessment value for stakeholder decision-making, and improve public perceptions, and offered additional technical improvements (NRC, 2006c). The NRC committee validated the technical merits of the assessment methods, models, and processes associated with root causes of the levee breaches, simultaneously suggesting deeper analysis into potential alternative root causes, and schedule extensions to accommodate additional investigation.

3.22 Volume VIII Risk Assessment and Final Review

Two years after the final draft 90% review, the NRC committee evaluated Volume VIII of the risk assessment and risk methods for New Orleans. The committee cited assessment strengths included levee system risk flexibility pre- and post-Katrina which can be modified and changed over time as needs warrant. The committee also identified several aspects of the risk assessment advanced the state-of-the-art using probabilistic methods (NRC, 2008c). Criticisms of the assessment involved explanation gaps regarding assumptions, logic and limits of the risk

assessment, including a lack of complete presentation of the results or the method employed to achieve the results (NRC, 2008c).

According to the committee, Volume VIII needed additional explanation regarding the Joint Probability Model, including justification and explanation for the number of storms as inputs to the model and a descriptive qualification of traits the number of storms represented. Table 10 contains twelve recommendations, six of which are repeated based upon earlier reviews.

NRC Committee Recommendations – Final Volume VIII Risk Assessment	
Chapter 1:	Valid overall assessment method. Assessment advanced the state of the art.
Chapter 2:	Incomplete methodology validation and explanation used to obtain results. (repeated)
Chapter 3:	Encouraged USACE to allocate necessary resources for timely completion.
Chapter 4:	Draft report contained errors. Careful documentation of assumptions, data and models. (repeated)
Chapter 5:	Finish uncertainty assessment quickly, while maintaining the rigor.
Chapter 6:	Develop a communication plan to increase assessment value for the public.
Chapter 7:	Complete additional soil and I-wall evaluations, along with explanations regarding single location points instead of system segments (repeated)
Chapter 8:	Increase climate change analysis depth and breadth.
Chapter 9:	Use flood inundation maps to validate the models. (repeat)
Chapter 10:	Explain Joint Probability Model details regarding variables and usage. (repeat)
Chapter 11:	Consider including a resettlement and reconstruction analysis.
Chapter 12:	Conclude the study quickly. (repeat)

Table 10 NRC Recommendations of IPET Volume VII Risk Assessment and Risk Methods

As New Orleans struggled to rebuild, the IPET effort contributed to understanding technical root causes of breaches and flooding. In addition to technical

expertise and recommendations regarding hurricane protection system improvements, IPET included public risk communication and perception management strategies.

3.22.1 *DRMS*

3.22.1.1 Initial Conditions

DRMS responded to a California Department of Water mandate in Assembly Bill (AB) 1200 to conduct a risk assessment of delta levees, including maintaining water quality and land preservation. Passed in 2006, the focus of AB 1200 enumerated nine areas related to the Delta, including an assessment of the antiquated levee system. The assessment of each area was provided to the legislature in a report by January 1, 2008 (URS Corporation, 2009; Duffy, Armstrong, Maurer, & Mitchell, 2006). In contrast to the nine areas specified in the original legislation, the original report covered some of the nine areas, and expanded on others outside the legislation (CALFED Independent Review Panel, 2007).

With respect to transparency, the IRP criticized DRMS inconsistent risk assessment methodology. The reviewers were unable to follow the process or reproduce the methodology throughout the assessment. The IRP indicated that the report is missing critical analyses, including a thorough probabilistic risk assessment, prohibiting following the analysis through the report to the end (CALFED Independent Review Panel, 2007).

According to the IRP, the DRMS initial Phase I report failed to articulate the assumptions and a proper accounting methodology of the uncertainty. Additionally, the overall integration of the risks from the sources specified in the legislation is

missing. The IRP further points out the report overlooks the impacts to the aquatic life within the assessment and the impacts to the Delta ecosystem.

The DRMS legislation specified assessing infrastructure, after witnessing the Hurricane Katrina levee system devastation. AB1200 outlined a two-phase decision-making process: Phase I was the assessment regarding levee safety and Phase II was the mitigation selection from potential options. The two-phase effort failed to materialize in the initial risk assessment report (California Legislature, 2005; CALFED Independent Review Panel, 2007; California Departments of Water Resources and Fish and Game, 2008). Originally intended to provide a decision-making mechanism for Delta levees, the initial report was found inadequate (CALFED Independent Review Panel, 2007).

Item 9 in the DRMS legislation suggested the Department of Fish and Game rate each option's impact on salmon restoration within the Delta and its tributaries (California Legislature, 2005). The IRP sought a comprehensive ecological risk assessment of the Delta, which is a broad interpretation of the original legislative purview (CALFED Independent Review Panel, 2007).

URS, the risk assessment contractor, suggested the DRMS legislation was specific to the levees and associated risks, thus narrowing the focus to levee system (URS Corporation, 2007). URS' response to the initial IRP review indicated that elaboration regarding risk assessment methods would not change the risk assessment results. Further, URS pointed out the largest levee system risks remained seismic. URS agreed that the treatment of uncertainty could be and would be improved with further work (URS Corporation, 2007).

The DRMS Phase I report failed the adequate documentation standard (CALFED Independent Review Panel 2007). The reviewers found five broad missing elements, identified as Tier 1 Issues. The reviewers elaborated on specifics within each element as a Tier 2 issue. Table 11 contains the five broad areas reviewers found in the initial Phase I DRMS report, with examples of each Tier 2 deficiency.

Review of the Delta Risk Management Strategy Report, Phase 1	
<i>Tier 1 Issue</i>	<i>Tier 2 Examples</i>
Analyses lacked transparency	Poorly written; undocumented assumptions and methods; risk terminology used interchangeably; expert reviewers had difficulty following the logic. Panel indicated the report failed the adequate documentation standard.
Limited carry-through of analysis to end	Failure to deliver complete probabilistic risk assessment. Narrow seismic and hydraulic hazard scenarios assessed; report departs from the documented plan. Lack of comprehensive scenario development and evaluation.
Limited treatment of uncertainty	Uncertainty is treated as a discrete quantity, without propagation through the analyses and limited to a few parameters. Substandard evaluation of uncertainty leads to questionable results.
Disjointed analyses – lack of integration	Unclear links between multiple models and assumptions associated with each model. Missing QA/QC processes regarding data management associated with multiple models.
Insufficient impact assessment on aquatic resources	Ecosystem assessment methodology description does not align with what was actually done. Lack of justification for what appears to be a new method for assessing risks to fish species.

Table 11 DRMS Initial Condition Phase I Report Issues

California leaders formed three other Delta conservation and risk assessment efforts: the Delta Bay Conservation Plan, the CALFED Ecosystem Restoration Program, and the Delta Vision, which utilized the levee breach assessment information contained within the DRMS reports (MWD, 2011). Authorization of three parallel efforts regarding Delta hazard assessment, coupled with reviewers interested in different risk assessment deliverables than URS provided suggests misaligned goals of the DRMS levee assessment authorization and independent reviewers' expectations.

3.22.1.2 Updated Assessment and Updated Decisions

3.23 Draft 4 Phase I Assessment

The updated Draft 4 Phase I assessment indicated flooding risk due to seismic and levee seepage hazards, with seismic risk assessed as the highest risk to the levee system (CALFED Independent Review Panel, 2008). According to the CALFED IRP, Phase I Draft 4 risk assessment addressed most of the initial issues, enabling Draft 4 Phase to serve as input into Phase II development of strategies and mitigation efforts to reduce the Phase I identified risks (CALFED Independent Review Panel, 2008). However, the IRP issued a caveat to the sufficiency, advising stakeholders consider the predictions as directional indications of effects, instead of direct literal interpretations of the risk, due to the 50-year and 100-year timeline projections.

For a second time, similar to the initial condition assessment, the IRP noted deficient ecosystem analysis in the Draft 4 Phase I assessment (CALFED Independent Review Panel, 2008). Reacting to New Orleans' devastation from

Hurricane Katrina, AB1200 emphasized the levee system and infrastructure risks, including holding to the co-equality of water provision and ecosystem assessment (California Legislature, 2005). IRP criticisms regarding lack of Delta ecosystem assessment conflicted with the genesis of the original legislated intent, thus suggesting a disconnect among the risk assessment stakeholder perceptions relative to the assessment emphasis and purpose. This disconnect has been articulated as co-equal, yet competing, goals of Delta water consumption for human interested balanced against Delta water conservation for animal and plant sustainability (Lund J. , et al., 2008; Lund J. , et al., 2010).

3.24 Phase II

According to the Phase 1 executive summary, DRMS Phase 2 originally intended to evaluate risk-reduction options for Delta levees long-term (DWR, 2009). Further, Phase I indicated proposing a new plan for the Delta Region beyond the purview of DRMS. Instead, DWR indicated Phase 2 would contain possible actions and a Delta strategy toward reducing levee failure risks and impacts (DWR, 2009).

DRMS Phase 2 evaluated the Phase I risks from a statewide economic impact perspective along three objectives: evaluation of risks and impacts to Delta levees from all sources over time; propose management criteria for Delta policy development; and, develop a levee-failure risk management strategy (DWR, 2011). These three objectives captured the legislated intent of evaluating potential impacts on Delta water supplies, included a plan for the Delta region, yet avoided improving or maintaining Delta water quality (California Legislature, 2005; DWR, 2011).

Similar to the questionable attainability regarding co-equal goals of water provision and ecological management, DRMS became centered politically on Delta water resources instead of remaining focused on the levee system risks. Phase I authors clearly stated the Phase 2 would avoid suggesting a Delta plan. The Phase 2 evaluation of water supply impacts included a Delta management plan.

3.24.1 *Coeur d' Alene*

3.24.1.1 Initial Conditions

Initial conditions associated with Coeur d' Alene depends upon the interest and perspective of the investigator. From a legal perspective, the initial conditions associated with mining in the Coeur d' Alene river basin stimulated multiple legal challenges and perspectives. From an environmental perspective, the NRC recommended several suggestions EPA could employ to improve Superfund designation processes and methods.

From a risk assessment perspective, the NRC suggested multiple improvements regarding methods and processes. The analysis here focuses on the risk assessment probabilistic model developed by URS Greiner and CH2M Hill. The NRC found several shortcomings, with Dr. Crouch on the committee providing specific criticisms regarding terminology, methodology and conclusions based upon faulty methods.

3.25 Untested Hypothesis

The PTM suggests the remediated volume of material is proportional to the load reduction from a remedial action for metals from a given source. Dr. Crouch

indicates this is an unjustified hypotheses. The PTM neglects to provide data or plausible theories connecting the proportionality of volume of material to the load reduction via a given source and a remedial action.

The small probabilities developed within the PTM resulted in Dr. Crouch questioning their validity. Using small numbers and probabilities, the PTM references effective mass of contaminated material available for leaching pre and post remediation, along with the respective change in material mass. The magnitude of the geographic area coupled with the small number of samples relative to the area size leads to questions regarding validity of small numbers and associated probabilities within the PTM (NRC, 2005).

3.26 Time Variation

PTM incorrectly assumes a constant decay rate for all times and all remediation scenarios, thus treating time variance as a constant. Time decays are typically exponential functions and not constant functions. The PTM introduced relative loading potential (RLP) defined as a metal leaching rate from contaminated source material, such as soil. Dr. Crouch suggested the assumption of a constant decay rate misrepresented the total mass of metal available for leaching. As the amount of leachable metal varies across an area, a constant decay rate leaves little room for a variable decay rate relative to the quantity of leachable metal available. In addition to the metal decay rates, the PTM indicated the decay rate of the annual average loading for all remediation processes is a constant, independent of the remediation methods, including no remediation.

3.27 Un-validated and Nonreproducible Values for Parameters Values

The PTM assessment uses quantitative estimates as input values, particularly for the relative loading potential (RLP_j) estimates and remedial action effectiveness (R_{ij}) estimates. These values are derived via qualitative descriptions. The qualitative descriptions result in relative loading and remedial effectiveness quantities somehow.

For example, the PTM suggests metal concentrations, leaching and erosion exposures, analysis of simple loading models, and professional judgment contributed to determining the RLP. Uncertainty within the RLP quantity uses expected value and variation coefficient, and the assumption the uncertainty follows a lognormal distribution. Dr. Crouch indicates data regarding mobility, exposure to leaching, or erosion are presented. The PTM neglects to identify the simple loading models used or how the models were used. Regarding professional judgment, the PTM neglects to connect the professional judgment with the site and influences upon the judgment.

3.28 Incorrect Probabilistic Analysis

Dr. Crouch documented discrepancies between the PTM and reasonable risk assessment logic and practice. The PTM combined time variation of a physical quantity with its uncertainty. For example, the PTM confused changes in loading in the Coeur d' Alene river with estimates of the remediation factor. The PTM suggested variability is the combination of both irreducible uncertainty associated with a physical phenomenon, and the probabilistic nature of the phenomenon. Thus, the PTM fundamentally confused variability with uncertainty.

3.28.1.1 Updated Assessment and Updated Decisions

EPA limited its assessment regarding Coeur d' Alene to the 2005 review. Thus, an updated Coeur d' Alene risk assessment with updated decisions remains open.

Chapter 4: Risk Perceptions Inform Stakeholder Decisions

Stakeholders perceive project risks and informed decisions differently, based upon individual frames of reference (Kleindorfer, Kunreuther, & Schoemaker, 1993; Fischhoff & Kadvany, 2011). Using the risk assessment process shown in Figure 3, each case analysis connects how the risk assessment(s) informed management decisions through stakeholder perceptions and communication. Foundations of the Risk Management Plan (RPM) involve expanding risk registers used in current practice. The RPM concept includes capturing and addressing stakeholder perceptions, using perceptions to develop risk communication plans, thus informing management decisions and increasing assessment value.

The RPM plan captures stakeholder perceptions through iterative collaboration between risk engineers and social science experts; subsequently enabling management decisions through appropriate stakeholder communication (Section 4.1 Managing the Risk Analysis Process). Using the RPM leads to increased value-add of the assessment process (Section 4.2 Risk Perception Management). Collaborative communication facilitates capturing stakeholder perceptions throughout the risk analysis process, improving risk analysis value.

The 1983 Red Book recognized potential conflicts of interest when risk analysts deliver assessments and also make risk management decisions. To avoid this conflict, the Red Book suggested separating analysts and managers (NRC, 1983). Risk assessment practice in the federal agencies resulted in multiple interpretations regarding the conceptual separation between analysts and managers. The RPM concept suggests collaborating with social experts toward closing the separation while simultaneously avoiding conflicts of interest.

Separation between analysts and managers resulted in inconsistent decisions within some agencies, leading to disconnected risk analysis processes (North, 2003). For example, the Department of Health and Human Services (DHHS) process developed antagonistic, ineffectual sub-agencies failing to deliver risk assessments and associated management decisions (Johnson B. L., 2003). Johnson (2003) describes how DHHS developed and documented a risk assessment/risk management policy leading to the process' ultimate abandonment due to "Balkanization" within the agency (p. 9). Lacking sufficient agency leadership, cross-functional teams developed and documented risk analysis practices, ultimately failing due to bureaucratic misalignment and lack of leadership (Johnson B. L., 2003). Federal agencies developed and abandoned risk assessment processes (Burke, 2003; EPA, 1989; EPA, 1992; EPA, 2000; GAO, 2006; Suter II, Norton, & Barnthouse, 2003; Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997; Morgan, Henrion, & Small, 1990).

Finkel and others suggest risk management begins through iteratively articulating decisions prior to conducting analysis, using the needed decisions as

inputs to plan the technical assessment (Finkel, 1993; NRC, 2008; NRC, 2005). Finkel (1993) explicitly refers to, “decision-driven assessments instead of assessment-driven decisions”, suggesting the decisions at hand inform developing the risk assessment process, instead of analysts planning the assessment to meet a risk management deliverable (p. 14). Planning risk assessment activities connected to the decision at hand has been repeatedly recommended since the Red Book (EPA, 2000; Hoch, Kunreuther, & Gunther, 2001; NRC, 1996; NRC, 2008; Presidential/Congressional Commission on Risk Assessment & Risk Management, 1997).

4.1 Managing the Risk Analysis Process

Risk analysts issue deliverables designed to inform decisions. General risk analysis practice includes creating a risk register, using technical software tools to analyze the hazards, and delivering a report compiling the results. Generally, risk management deliverables focus on technical aspects of risk analysis and assessment, as they should.

Technical focus cannot be overstated; historically, complex project deliverables overlook stakeholder management elements associated with perceptions and communication planning. The case analysis within this study connects stakeholder management of complex projects to perception management and risk communication. The cases contain varying degrees of perception management and communication planning, demonstrating the novel process with varying degrees of success.

In addition to the risk register, an RPM contains multiple perceptions associated with each option, and a mitigation path to achieve stakeholder agreement. Social experts developed multiple methods regarding capturing stakeholder perceptions and including perceptions into decision-making processes (Fischhoff & Kadwany, 2011; Hoch, Kunreuther, & Gunther, 2001). Social experts suggest capturing stakeholder perceptions at the outset to inform which method improves decisions. The process includes verifying connectivity between decisions and hazards.

The cases selected for this study represent a variety of analytical risk assessment process techniques. If risk assessment remains defined as simply providing predictions and probabilities, the technical assessments reflect efficacious results for each case. Assessment processes in this study refer to systematic risk assessment processes capturing stakeholder perceptions associated with complex problems, informing whether the assessment provided value to enable decision-making.

Discussed prior in Section 2.4.3 Red Book 2008 Update, the NRC published an updated risk assessment process suggesting iteratively connecting risk assessment deliverables to hazards (NRC, 2008). Based upon studying these cases, the risk assessment process suggested in Figure 3 suggested involves collaborating with social experts to develop risk assessments to capture stakeholder perceptions connected to project hazards identified within the risk register. The risk perception management plan (RPM) concept guides experts regarding capturing stakeholder perceptions aligned to the decisions at hand, including iterating changes in the alignment and/or perceptions as the risk analysis process progresses.

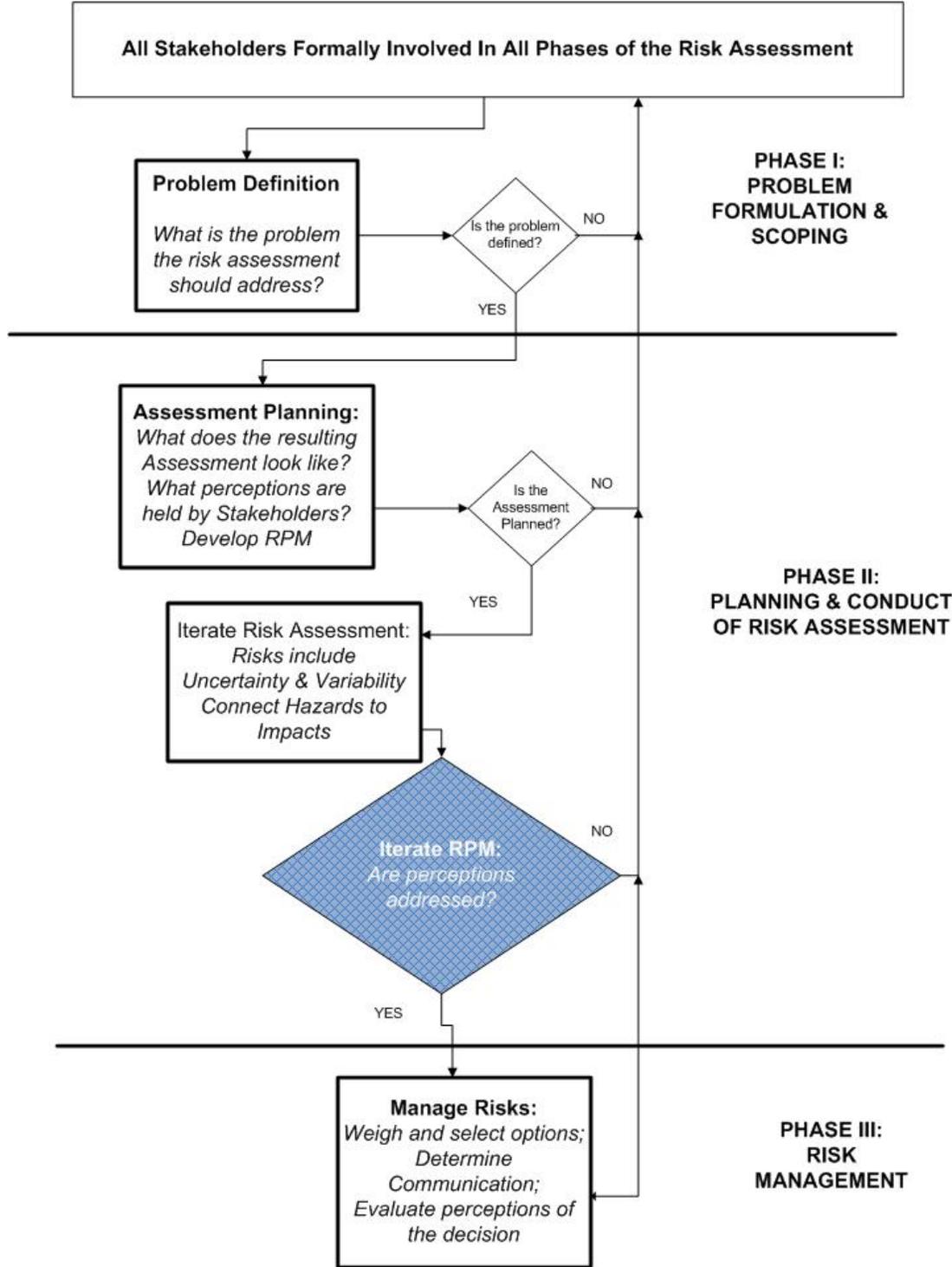


Figure 3 Risk Assessment Process including Risk Perception Management

4.1.1 *National Bio- and Agro-Defense Facility (NBAF)*

The NBAF case demonstrates issues regarding stakeholder perception management coupled with risk communication management. DHS neglected to address stakeholder perceptions regarding agency capability to contain lethal pathogens in the event of a release; neglected to adequately address stakeholder concerns associated with locating the laboratory in Tornado Alley; and neglected to adequately address technical aspects of the risk assessment raised by risk analysis experts (NRC, 2010b; NRC, 2012; Concerned Citizens, 2008). Technical risk analysis issues included lack of uncertainty analysis; flawed technical assessment modeling with respect to tornado models; questionable modeling projections of potential FMDv spread; and seemingly random initial assumptions regarding epidemiologic, wind and pathogenic disbursement models (NRC, 2010b; NRC, 2012).

Recall from Chapter 3: DHS received presidential direction to protect citizens from terroristic threats, including infectious agents. Evidence in the literature suggests DHS perceived presidential direction included a new state-of-the-art BSL-4 agro-defense facility designed to conduct research to keep the country safe from lethal pathogens, including foot-and-mouth-disease virus (FMDv) (Bush, Presidential Directives, 2001; DHS, 2008). The literature further indicates stakeholders, including the GAO, Congress, NRC experts, and the public, perceived DHS lacked the capability to contain FMDv within a biosecurity facility on the U.S. mainland (GAO,

2008; GAO, 2009; NRC, 2010b; Concerned Citizens, 2008; 111th Congress, 2009). In addition to pathogen containment concerns, NRC experts questioned DHS's risk analysis expertise (NRC, 2010c). These recognized deficiencies, coupled with stakeholder awareness of the United States' FMDv-free status since 1929, resulted in contention between state officials and Kansas residents (GAO, 2008; GAO, 2009). In light of the concerns, DHS pressed forward, selecting Tornado Alley in Kansas as the NBAF site, ignoring community, state and federal stakeholders' concerns regarding preventing an FMDv release, and containment in the event of an FMDv release (111th Congress, 2009; Concerned Citizens, 2008; NRC, 2010; NRC, 2012). Beef industry economic impact estimates in the event of an FMDv release varied widely. Evaluating the two opposing websites suggests stakeholders talking past each other instead of conducting a collaborative conversation working toward resolving concerns (Concerned Citizens, 2008; State of Kansas, 2009).

NRC risk analysis experts repeatedly documented similar deficiencies contained within duplicative risk assessments (Signature Science LLC, 2010; Signature Science, LLC, 2012; NRC, 2010; NRC, 2012). Congressional action reflected skepticism when the House voted to remove \$404M from NBAF for construction based upon safety and cost concerns, thus halting the NBAF in Kansas (U.S. House of Representatives, 2013). During the 2013 floor debate, Representative Bishop from New York cited the two NRC reviews regarding risk assessment and associated safety, questioning DHS capability to prevent potential FMDv release; contain a potential FMDv infectious spread; and questioned the ballooning cost from

451M to \$1B, although Bishop's interest conflicted with moving the laboratory from his home state of New York.

The House voting record documents lack of support for NBAF in fall 2013, including Kentucky Rep. Rogers vote to remove funding, followed by Rep. Rogers' vote to restore funds in January 2014 a few brief months later (U.S. House of Representatives, 2013; U.S. House of Representatives, 2014). Rep. Rogers chairs the House Appropriations Committee, raising open questions regarding congressional support changes. Rogers, a Kentucky representative for 30-plus years, is well-known in his home state for bringing federal dollars into impoverished Appalachian Kentucky counties. Rogers' shift toward releasing funds for NBAF opens more questions about congressional perceptions overriding local community concerns.

Kansas political stakeholders perceived NBAF economically beneficial (State of Kansas, 2009). Kansas elected officials ignored expert assessments of DHS risk assessment capability, and instead focused on the economic impacts of the laboratory. In spite of NRC expert critical assessment of the two DHS site-specific risk assessments; and in spite of concerns raised by local Kansas residents; Kansas officials moved forward singing praises for securing the laboratory and its potential economic and employment benefits (Concerned Citizens, 2008; State of Kansas, 2009; NRC, 2012; NRC, 2010b).

State and federal leaders' myopic view of near-term \$3B economic impact for the state compared to the long-term potential \$50B negative economic impact should FMDv escape clouded federal funding decisions (U.S. House of Representatives, 2014). The state stakeholders ignored the potential impacts associated with losing

“FMDv-free” status (GAO, 2008; GAO, 2009). GAO (2008; 2009) and NRC (2010b; 2012) experts repeatedly warned stakeholders regarding DHS BSL-4 laboratory-management capability; questioned DHS capacity to manage a potential FMDv release in an area of potentially highest economic impacts; illuminated the magnitude of potential global beef industry economic impact in the event of an FMDv release; and questioned DHS’ ability to restore FMDv-status in a timely fashion.

In spite of the litany of concerns perceived by the majority of stakeholders, DHS managed to reverse congressional perceptions regarding the low probability of release and the low economic impact, convincing Congress to restore construction funding. The connection between Rep. Rogers as Chair of Appropriations and DHS remains cloudy. On January 15, 2014 the House of Representatives Appropriations Committee reinstated \$404M for NBAF construction (U.S. House of Representatives, 2014).

The NBAF risk analysis process lacks transparency, clarity, and repeatability, key components established by other agencies and endorsed by independent experts (EPA, 2003; EPA, 2000; NRC, 2008). The leaders driving the process neglected to iteratively account for stakeholder perceptions regarding laboratory operation and safety; neglected connecting perceptions to critical DHS expertise and management questions raised by experts, using a process suggested by experts; and instead forged ahead without satisfactorily addressing concerns (Concerned Citizens, 2008; State of Kansas, 2009; NRC, 2008; NRC, 2010b; NRC, 2012).

NRC reviews experts highlighted NBAF technical risk assessment issues: lack of uncertainty analysis; selecting apparent random assumptions; leading to

criticism of low risk of infectious release, and an inaccurate representation of risks associated with operating the laboratory and specifically conducting FMDv research (NRC, 2010b). Experts reviewed the second assessment found similar deficiencies (NRC, 2010b; NRC, 2012). The expert reviews were limited to the technical aspects of the assessments and skills. Review of NBAF risk assessment shortcomings, and DHS risk assessment skill gaps, fell short with respect to political perception management. NBAF serves the research purpose because the disconnected politicians and local community share differing perspectives, with little documented effort to bridge the two.

The Kansas government established a website documenting the positive impacts and support for the facility including the positive economic impact of \$3.5B over 20 years in Kansas (State of Kansas, 2009). A group of concerned citizens established a website questioning the validity of DHS risk assessments where NBAF skeptics point to the potential \$50B national economic impact should a release of FMDv occur (Concerned Citizens, 2008; NRC, 2012).

DHS discussed a Stakeholder Engagement Plan in the SSRA and uSSRA appendices, including establishing a Stakeholder Engagement Committee (SEC) and specific activities (DHS, 2010; DHS, 2012). The DHS website containing NBAF documentation and reports lacks available evidence regarding the stakeholder engagement activities. Undocumented purpose and activities of the SEC suggests questioning the validity of such a committee.

The SEC could potentially refer to the Kansas Steering Committee, although a direct connection remains unclear. DHS lacks documentation regarding conferences,

websites, and meetings with academics and experts regarding NBAF and laboratory practices. Construction of the NBAF utility plant continues, with an unanswered question regarding whether FMDv can be conducted safely on the US mainland, compared to as safely as on Plum Island. Congress has been convinced, as of January 2014. The public remains unconvinced. As a constructive aid toward building bridges within the community, DHS should consider delivering the activities documented in the uSSRA Appendix A Stakeholder Engagement Plan (Signature Science, LLC, 2012).

4.1.2 *National Emerging Infectious Diseases Laboratories (NEIDL)*

NEIDL demonstrates increasing risk assessment value through the lens of process improvements by iteratively evaluating stakeholder perceptions and addressing perceptions through a crisp communication plan. Thus, NEIDL informs this research regarding increasing risk assessment value.

NIH developed a biodefense research agenda based upon the anthrax mailings in 2001 (NAID, 2003). Boston University (BU) responded to DHS's request for proposals and won the NEIDL award, one of two national biosafety level 4 laboratories (BSL-4) laboratories under consideration at that time (the second is the Galveston National Laboratory & Institute for Human Infections and Immunity operated by the University Texas Medical Branch at Galveston). BSL-4 laboratories serve research purposes on the world's most virulent pathogens, following strict international laboratory practice protocols.

NIH released the initial Final Environmental Impact Study (FEIS) assessing the merits of action compared to no action. Simply providing an FEIS indicating an “action/no action” assessment, NIH and BU underestimated the magnitude of negative community response (Boston Bar Association, 2014). The selected South Boston neighborhood had been deemed a federal social justice community, meaning the resident demographics were largely elderly, children and other underrepresented populations with little voice in neighborhood activities (NRC, 2007). Based upon this lack of representation, NIH and BU encountered a cohort of neighbors filing lawsuits to stop the laboratory construction (Boston Bar Association, 2014). Law firms represented disadvantaged neighbors and community groups *pro bono*, raising questions in the court system about laboratory safety and security, causing project delay (Boston Bar Association, 2014).

BU contributed to the lack of community confidence through apparent neglect to inform state and community stakeholders regarding tularemia infections in fall 2004 and a BSL-3 lab fire in spring 2005 (Boston Bar Association, 2014). Review of Boston Bar Association case progression documentation (2014), in December 2006 the court ordered NIH rework the risk assessment to achieve compliance with NEPA. NIH subsequently argued such compliance unnecessary, to which the judge disagreed (Boston Bar Association, 2014). Facing with compliance or appellant options, NIH instead recognized the courts’ collaboration assessing the supplemental risk assessment inadequacies. Judges in both cases cited similar concerns, concurring together ordering NEPA compliance in late 2006, to which NIH agreed in January 2007 (Boston Bar Association, 2014). NIH subsequently announced the Blue Ribbon

Panel (BRP) to assist development and communication of the court-ordered NEPA-compliant risk assessment. NIH compliance with court orders, coupled with establishing the BRP suggest the agency recognized stakeholder perception problems, and began demonstrating stakeholder management connected to risk assessment communication process improvements.

Using the framework suggested by this research and documented in Figure 3, the NEIDL case suggests a real-time connection between stakeholder perceptions and failure to inform stakeholders of a problem. NIH neglect to inform officials about the tularemia infections and the fire suggest an understandable unwillingness to share required internal problems with the public. In practice, admittedly few organizations voluntarily share internal issues with stakeholders, instead working to resolve problems before a leak occurs to provide stakeholders with a general sense of confidence. Generally, many engineers practicing in industry are trained to offer suggestions at the time of problem identification. Anecdotally, business books describe managers attesting to bringing problems in hand with solutions. With respect to risk analysis, describing problems and solutions simultaneously removes stakeholders from the process; contributes to risk analysis confusion; and enables disconnection between comprehensive risk assessments and potential complete solutions (Kleindorfer, Kunreuther, & Schoemaker, 1993; Hoch, Kunreuther, & Gunther, 2001; RAE, 2003).

NIH and BU partnering to construct the NEIDL coupled with BRP and community feedback throughout the process demonstrates federal agencies using Figure 3 to iteratively capture stakeholder perceptions and develop communication

plans. Prior to establishing the BRP and developing an assessment process including community stakeholders and communication, NIH neglectful information exchange reinforced stakeholders' NIBMY syndrome, and reinforcing negative laboratory safety perceptions (Boston Bar Association, 2014; Jahnke, 2013). To facilitate transparent communication, the BRP and the NRC review committee discussed the supplemental risk assessment throughout the process, suggesting NIH fully incorporate NRC and community concerns into the assessments as they were developed (NRC, 2010; NRC, 2010a; NRC, 2011b). NIH announced the Blue Ribbon Panel (BRP), a committee of experts convened to advise the agency regarding appropriate responses to litigation, community concerns and the initial critical NRC report (NIH, 2009).

Between mid-2006 and early 2007, NIH and BU began to understand the impact risk communication bears on the process associated with public acceptance of a biosafety lab. NIH's actions demonstrate the connection between informing officials about a problem (or neglecting to inform), with improving stakeholder management and communication associated resolving community contention. The NEIDL case demonstrates the evolution regarding meeting federal and state requirements with a risk assessment into a public community relations communication platform (NIH, 2009).

Choosing to comply with court mandates, coupled with the establishment of the CLC, reflects an agency turning from isolated operations into the beginning of a community partner. Legal milestones reflect a change in tone by NIH from condescending to cooperation when NIH offhandedly indicated a NEPA-

noncompliant attitude, until the judges ordered NEPA compliance (Boston Bar Association, 2014). In addition to NEPA-compliant standards, BU established a six-member Community Liaison Committee (CLC), which conducted seven public forums to capture community concerns regarding research safety; raise community educational awareness regarding laboratory safety measures; and increase community cooperation regarding facility operation through providing open house tours (Laskowski, 2007). To insure transparency, the committee eventually expanded from the initial six to nine members from across Boston, including three from the South End directly (Four Point Associates, Inc., 2013; Boston University Medical Campus, 2014). Beginning in 2008 and throughout the process, BU plans and programs regarding interactions with the community involved open houses, educational events, and open public forums to discuss research plans and activities (Four Point Associates, Inc., 2013). The Suffolk Superior Court ruled in May 2014 that the Supplemental Final Environmental Impact Review (SFEIR) met NEPA requirements, reflected a comprehensive risk assessment, and established the operational security of NEIDL (Jahnke, BU Today, 2014; Sanders, 2014). As of mid-2014, NEIDL awaits final approval from the Boston Public Health Commission to conduct BSL-4 research (Jahnke, 2014)

4.1.3 *Fort Detrick*

The risk analysis process used during the Fort Detrick facility expansion fell short from a management perspective, as well as technically (NRC, 2010d). Through the lens of the 2001 criminal anthrax mailings originating from Fort Detrick which

killed five postal workers and sickened many others, experts questioned the risk analysis credibility and adequacy, from both community communication and technical laboratory process protection perspectives (NRC, 2010d). Laboratory infections acquired by workers fueled community apprehension regarding the expansion (NRC, 2010d). The reviewers strongly suggested agency use of proven risk assessment communication processes (NRC, 2010d). The Army, as the agency responsible for the lab expansion, overlooked these recommendations, serving as an example in this case study which could benefit from communication and perception management practice.

Expert independent review of the USAMRIID facility at Fort Detrick was originally mandated by Congress (NRC, 2011; NRC, 2010d). After the initial critical reviews, the Army recognized the value these reviews provided, requesting further expert review and constructive feedback (NRC, 2011; NRC, 2010d). In addition to already-mentioned deliberate anthrax exposure, Fort Detrick has a history of laboratory-acquired-infections (LAIs) (NRC, 2011c). Despite these assessment process shortcomings, risk communication and stakeholder perception management processes utilized during facility expansion planning changed little.

The NRC found the USAMRIID risk assessment incomplete, indicating the most credible events were not foreseeable and suggesting the Army expand risk communication paths with the local residents (NRC, 2010d). The community recognized the history of LAIs, increasing community apprehension regarding infection spread from the facility (NRC, 2010d). The experts documented the contractor perception of the risk assessment work plan as a hurdle to overcome,

instead of an opportunity to collaboratively resolve community stakeholder fears and communicate risks appropriately (NRC, 2011).

Fort Detrick facility expansion demonstrates insufficient stakeholder perception management because the Army requested NRC review as a step forward to build communication for the laboratory. The Army overlooked expert suggestions regarding applying an iterative risk assessment framework; failed to include community stakeholders in the assessment process; and ultimately moved forward without regard to the neighborhood concerns (NRC, 2011; NRC, 2011c). The Army missed an opportunity to collaboratively develop a comprehensive risk assessment stakeholder management process accounting for stakeholder perceptions and including risk communication methods.

4.1.4 *Interagency Performance Evaluation Task Force (IPET)*

The IPET project demonstrated the stakeholder management process connection to risk perceptions and communication suggested within this study. Throughout the assessment development process, the review committee repeatedly suggested delivering the assessment in both technical and laymen's terms (NRC, 2008c; NRC, 2006; NRC, 2006b; NRC, 2006c; NRC, 2009). Reviewers recognized providing the assessment to a nontechnical, broader public audience increased risk assessment value to community stakeholders. From the outset, IPET team leaders developed collaborative public engagement throughout the hurricane protection system assessment process via public forums and feedback mechanisms (NRC, 2008c; NRC, 2009). The IPET leaders built the collaborative stakeholder

management process as the assessment progressed, iteratively demonstrating stakeholder management process improvements to such a degree that IPET was held up as a process model for the Delta Risk Management Strategy (DRMS) in California. IPET demonstrated including stakeholder perceptions regarding risk via developing a risk perception management plan.

Throughout the analysis process, reviewers suggested IPET include risk communication and risk perception elements into the risk assessment to facilitate improved decision-making and public understanding, and involving the community and providing information in terms easily understandable by the public (NRC, 2008c; NRC, 2009)(NRC, 2006; NRC, 2006b; NRC, 2006c). The NRC committee suggested IPET iterate the assessment, including providing information to simultaneously increase risk awareness and also allay public fears regarding living in a hurricane zone (NRC, 2006). The NRC strongly suggested connecting the societal and communal hurricane risk to the technical assessment of specific protection system elements (NRC, 2008c; NRC, 2009). NRC review of Volume VIII, the final risk assessment, suggested connecting the technical assessment to overall system risk in laymen's terms to improve resettlement motivation (NRC, 2009). The IPET case validated in practice the novel idea of iteratively assessing risks, including capturing stakeholder perceptions via public comment and input, thus increasing risk assessment value for stakeholder decision-making.

The primary contribution IPET makes to this study revolves around New Orleans residents risk perceptions connected to living in a hazard-prone area. The

NRC accurately pointed out IPET contributions to assessment and geologic state-of-the-art technical advances (NRC, 2009).

Conversely, the NRC pointed out New Orleans' neglect to develop and implement comprehensive hurricane preparedness. The lessons learned from Hurricane Katrina represent common knowledge by experts and practitioners regarding natural hazards, civil defense, emergency preparedness, and other suggestions are widely known and suggested prior to Katrina, suggesting New Orleans and vicinity had achieved a complacency with the hurricane protection system (NRC, 2009). IPET validates the study, short of specifically articulating the connection between an RPM and improved decision-making value. Experts suggested iteratively and collaboratively soliciting stakeholder feedback, and developing case connects iterative risk assessment processes with increased value for decision-making.

4.1.5 *Delta Risk Management Strategy (DRMS)*

Risk Assessment practice which delivers a report failing to meet the needs of the problem at hand remains a pervasive issue (Charnley, 2003; Anderson, 2003). The California legislature mandated a Delta levee system risk assessment with respect to improving and maintaining water quality, including assessing levee hazards (California Legislature, 2005). Reviewers criticized the lack of Delta ecosystem risks in the delivered assessments (CALFED Independent Review Panel, 2007; CALFED Independent Review Panel, 2008). The difference between the ordered deliverable and final risk assessment deliverable suggests stakeholders held misaligned

perspectives about the purpose of the risk assessment, pointing to issues within the Delta risk assessment process.

In the case of DRMS, needed decisions were articulated in the AB1200 legislation. Delta perceptions involve the politically-charged co-equal goals of human consumption balanced against ecological provision (Lund J. , et al., 2010; NRC, 2012a).

According to the IRP, the initial DRMS risk assessment failed to provide useful information to aid appropriate decisions. URS took issue with IRP Tier 1 comments (see Table 11), including seismic risks, and revised and updated the Phase I assessment (Salah-Mars & McCann, Jr., 2007). Originally due in January 2008, DRMS submitted Draft 4 Phase I report for review by the IRP in February 2009 (DWR, 2009).

Draft 4 Phase I risk assessment contained gaps, although less severe than the initial assessment, rendering this version suitable as an input to Phase II (CALFED Independent Review Panel, 2008). However, the IRP noted several caveats and concerns, including the continued missing ecosystem impact analysis. URS included in the updated effort clarity, transparency and traceability within the updated Draft 4 Phase I assessment, including quantifying risk numbers and percentages for the 50- and 100-year levee failures, perpetuated through the Final Phase I assessment (URS Corporation, 2009; CALFED Independent Review Panel, 2008).

The IRP suggested URS reduce the precision of providing a risk number or percentage to instead providing a general trend, given the long-term nature of assessing levee stability (CALFED Independent Review Panel, 2008). This

suggestion aligns with the suggestions from risk communication science, specifically regarding the brain's inability to process small numbers, and the human tendency to change decisions based upon changes in the risk presentation (Fischhoff & Kadavy, 2011; Hoch, Kunreuther, & Gunther, 2001). Although useful for the Phase II development of the mitigation strategies for the levees, the IRP suggested the updated Phase I report of the risks to the Delta be reviewed and utilized as input to Phase II with these caveats in mind.

The Phase II analysis was reviewed and commented upon by a stakeholder in the process, Metropolitan Water District of Southern California (MWD). The MWD depends upon the exports from the Delta to serve the population of the southern California. Delta residents infer MWD as a "bully" because of this relationship, questioning MWD motivation regarding Delta mitigation and risk assessment strategies (Delta Landowners, 2014). That said, the two primary issues MWD cited included a lack of ecosystem risk analysis associated with water exports, and the lack of economic building block analysis, both of which fall outside the original legislated scope of the DRMS AB1200 assessment. MWD's review fails to align with the Phase I Risk Assessment methodology of insuring the answers provided by the risk assessment remain pertinent to the questions posed by the problem, as outlined by the NRC in the 2008 updated Red Book risk assessment process (MWD, 2011; NRC, 2008).

After Hurricane Katrina in 2005, the state of California recognized their vulnerability to a similar potential devastation, although from a different source. The levees within the California Bay-Delta area are fast outpacing the current status quo

management practices, as pointed out by Lund and others (Lund J. , et al., 2008; NRC, 2012a).

To force the state to begin addressing the inevitability of a potential economic and infrastructure catastrophe, the California legislature passed Assembly Bill 1200 in 2005 authorizing the Delta Risk Management Strategy (DRMS). Simultaneously, the governor initiated several other complimentary efforts to address the overall Delta sustainability, in addition to the levee integrity and maintenance issues (California Departments of Water Resources and Fish and Game, 2008).

DRMS efforts inform this research through stakeholder disconnects. The initial Phase I risk assessment developed by URS failed the adequate documentation standard (CALFED Independent Review Panel, 2007). According to URS' response, the initial Phase I assessment accounted for levee assessments, overlooking water quality availability and maintenance (Salah-Mars & McCann, Jr., 2007). This disconnect suggests different stakeholder perceptions relative to the desired risk assessment deliverable and the resulting deliverable. The NRC recommended iterative risk assessment, including all stakeholders to insure alignment between the problems the assessment is trying to address and perceptions (NRC, 1994; NRC, 2008). The concept of an RPM could address closing the stakeholder perception disconnect by iteratively including stakeholder perceptions regarding the co-equal goals of Delta water consumption balanced with ecological sustainability. Speculatively, these goals could be ultimately unachievable. A process to determine solvability includes assessing stakeholder perceptions connected to Delta water consumption and ecological sustenance. There may be other processes as well.

Subsequent assessment revisions met the standard for usability regarding decisions (CALFED Independent Review Panel, 2008). DRMS disjointed risk assessment gaps, coupled with authorized disconnected Delta assessment efforts, demonstrate risk assessment process issues regarding iterating hazards and mitigation options relative to stakeholder perceptions, as the concept of an RPM suggests (NRC, 2008; Kleindorfer, Kunreuther, & Schoemaker, 1993; Hoch, Kunreuther, & Gunther, 2001).

4.1.6 *Coeur d' Alene*

Superfund megasite Coeur d' Alene informs this research on multiple levels. Originally this case was selected for inclusion based upon a critical NRC review of the contracted probabilistic risk assessment. Succinctly, EPA confused variability with uncertainty regarding assessing remediation models, pointing to the ineffectiveness within the agency to conduct and deliver appropriate risk assessments.

Upon further investigation, however, Coeur d' Alene provides a rich history regarding the research suggesting risk assessments include an RPM. The local residents and scientists of the early 20th century recognized evidence of the hazards. Instead of collaboration, conflict ensued, and litigation.

The Coeur d' Alene historical evidence is silent regarding the possibility of collaborating to develop a public-private partnership toward resolving pollution control issues balanced with corporate profits. The concept of such a partnership potentially applies to recent EPA mandates for carbon emissions, for example.

Coeur d' Alene provides education regarding environmental impacts due to corporate negligence, corporate resistance to evidence, and corporate will versus community will. The litigious history documents the magnitude of the chasm between corporate perspectives and public perspectives. An RPM aligned to a risk register developed for corporate capital investment could potentially service both public community and private industry interests.

Coeur d' Alene and its contamination apply to a variety of current environmental issues today. Fracking, for example, could benefit from a healthy dose of perception management bridging the gaps between environmentalists and corporate decision-makers. Liquid natural gas pipelines could benefit also. Stakeholders associated with these large, complex projects could, and this research suggests should, collaboratively iterate the risk assessment(s) to include perceptions, developing a perception management plan. The NRC has documented the benefits of stakeholders collaboratively evaluating the risk assessment to insure alignment between the decisions and the problem (NRC, 2008).

4.1.7 Managing Risk Analysis Processes

These cases suggest risk analysts have an opportunity to learn from history. The cases suggest including social science experts in a collaborative risk assessment planning process; clearly connecting risk assessment process decision deliverables to the hazards and problems under assessment; collaborating with social experts to capture stakeholder perceptions into the process; and delivering comprehensive risk assessments covering both technical and social perspectives regarding project

hazards. For too long risk engineers and risk managers have focused singularly on probabilities, projections, and quantification, overlooking increasing assessment value through comprehensive perception and communication process planning.

4.2 Risk Perception Management

The practice of risk management has traditionally involved investigation and quantification of potential hazards and their resulting potential occurrence, viewed through the lenses of potential impacts associated with each hazard (NRC, 1983; NRC, 2008). Social experts suggest limiting risk assessments to technical interpretations of probability and impact limits assessment value (Fischhoff & Kadvany, 2011; Botzen, Kunreuther, & Michel-Kerjan, 2014; Morgan, Henrion, & Small, 1990; Hoch, Kunreuther, & Gunther, 2001; Kleindorfer, Kunreuther, & Schoemaker, 1993). Little has been said in the risk assessment literature regarding extending the practice of risk management to include the perceptions held by the decision makers, and effects stakeholder perceptions have on decision-making.

Risk Perception Management involves articulating stakeholder perceptions at the outset of planning risk assessments. Social science experts suggest capturing stakeholder perceptions as a decision-making element for a variety of complex choices (Fischhoff & Kadvany, 2011; Hoch, Kunreuther, & Gunther, 2001). According to social scientists, perceptions, also referred to as frames of reference, contribute to human choice processes. The manner in which options are presented further complicates decision-making, creating a sociopolitical conflict regarding the decision data and available choices (Slovic, 2003). Framing issues across agencies to

include multiple perspectives has been lost as risk assessment process has evolved (Hattis & Goble, 2003). This study suggests including risk perceptions increases risk assessment value, facilitating improved decision-making.

The concept of risk perception management begins at the outset during problem definition and quantification of the decision at hand. The notion of an RPM is analogous to a risk register. As hazards become identified, the risk assessment team conceivably captures stakeholder perception(s) associated with each hazard. Agreement regarding perceptions remains the goal. Achieving agreement involves negotiation, deliberation, and communication. This study suggests including risk perceptions into the project management processes for large projects using a Risk Perception Management (RPM) plan connected to the risk register as the mechanism for including stakeholder perceptions regarding hazards into risk assessments.

4.3 Perception Confirmation

Economic, business, and decision models and metrics exist to establish the formal value of something. Confirming the value of a product involves answering the question, “Does the product function as intended?” From an engineering perspective, the question becomes, “Does the design meet the specification?” Confirming the value of a risk assessment involves answering the question, “Does the risk assessment address the problem at hand?” (NRC, 2008). Valuable risk assessments lead to risk management decisions including all stakeholders participating in the process (NRC, 2008). The cases in this study suggest valuable risk assessments iteratively address

these questions, including stakeholder perception management processes within the project communication plan.

A hurdle for many federal agencies regarding risk assessment involves capacity of agent personnel to iteratively include all stakeholders, taking time to plan the assessment, and then verifying the assessment addresses the problem (NRC, 2008). A missing element of risk assessment involves accounting for stakeholder risk perceptions, and communicating information appropriately to address risk perceptions and misperceptions.

Perceptions refer to frames of reference held by different stakeholders (Hoch, Kunreuther, & Gunther, 2001). The ultimate choices people make depends upon how a problem is framed (Hoch, Kunreuther, & Gunther, 2001). Excluding frames and perceptions, coupled with communication issues, results in suboptimal decisions, particularly as the problems become more complex (Hoch, Kunreuther, & Gunther, 2001; Fischhoff & Kadvany, 2011; Morgan, Henrion, & Small, 1990).

Improving risk assessments for decision making involves including independent reviewer recommendations, aligning risk assessment methodology to the updated 2008 NRC model (see Figure 3), and including a Risk Perception Management plan to evaluate stakeholder risk perceptions. Conceptually, the RPM reflects a formal plan capturing stakeholders' perceptions associated with each hazard contained in the project risk register. The NEIDL and IPET cases in this study demonstrate benefits of the suggested process.

NEIDL risk assessment began with a simple decision whether to build the laboratory, evolving during ten-plus years from a generic mandated EIS into a

comprehensive communication and perception management plan accounting for and including community perceptions regarding BSL-4 research in urban Boston (NAID, 2003; NIH (RWDI West, Inc.), 2005). As NIH comprehended the magnitude of community opposition and concerns, the process expanded. NIH established the BRP to dialogue with risk assessment experts, sought community feedback to inform risk concerns and expand the hazards under consideration, and eventually established a CLC specifically tasked with community engagement (Boston University Medical Campus, 2014; NIH, 2009; NRC, 2010; NRC, 2010a; NRC, 2011b). Incorporating and addressing community perceptions has enabled NEIDL to clear all but one final hurdle regarding permits to conduct BSL-4 research (BU Press Release, 2014).

IPET began as an assessment of the hurricane protection system before, during and after Hurricane Katrina (Link, et al., 2009). Initially designed as an assessment to prepare for the following hurricane season, IPET expanded from a technical risk assessment regarding levee failure modes, vulnerabilities and repair into a comprehensive plan coupling community perceptions and communication (NRC, 2006; NRC, 2006b; NRC, 2006c; NRC, 2008c). In addition to modeling risk communication planning, IPET advanced state-of-the-art hurricane prediction assessment from measuring wind speed into damage predictability (NRC, 2008c). IPET addressed community perception education regarding a false sense of security associated with living below sea level behind a complex system of levees designed and constructed with inconsistent different funding levels and managed from inconsistent management plans (Link, et al., 2009). IPET serves as a model for the suggested risk assessment process shown in Figure 3.

NBAF, DRMS, and Fort Detrick demonstrate the hazards associated with ignoring stakeholder perceptions. Coeur d' Alene stands as an expensive environmental example regarding the risk assessment ignoring scientific technical evidence and local community stakeholder perceptions regarding contamination hazards.

NBAF dysfunctional construction continues within the Kansas community (Concerned Citizens, 2008; State of Kansas, 2009). According to Concerned Citizens, state leaders' political motivation serves as self-promotion regarding the influx of federal dollars, with little regard to the potential hazards associated with losing FMDv-free status (Concerned Citizens, 2008). State leaders express unabashed optimism regarding future high-paying jobs and federal research opportunities, with little regard to lack of medical infrastructure necessary in the event of FMDv release, or the subsequent potential economic impacts (State of Kansas, 2009; NRC, 2012). Community stakeholders perceive government stakeholders have overlooked and ignored concerns of significant magnitude (Concerned Citizens, 2008; GAO, 2009; NRC, 2012). These differences suggest NBAF could benefit from an RPM.

Perception confirmation of DRMS involved politically complex issues (CALFED Independent Review Panel, 2008; MWD, 2011; DWR, 2013). Originally motivated as an assessment of the Delta levee system after New Orleans' Katrina devastation, DRMS became another element in a statewide political controversy regarding water management and availability (California Legislature, 2005; CALFED Independent Review Panel, 2007; CALFED Independent Review Panel, 2008; DWR,

2009; DWR, 2013; Lund J. , et al., 2010). According to Lund (2008) the co-equal goals of water availability and ecological restoration are unsustainable, suggesting the initial hazard perceptions of availability and restoration lack adequate exploration and development using the suggested iterative assessment process shown in Figure 3 Figure 3 Risk Assessment Process including Risk Perception Management. Expending additional resources conducting parallel efforts to DRMS supports suggesting the political nature of the DRMS effort, simultaneously failing to address the levee system vulnerabilities (MWD, 2011; NRC, 2011). DMRS confirmed perceptions remain limited to the co-equal unattainable goals of availability and restoration, instead of moving forward toward integrated levee infrastructure solutions (NRC, 2012a).

Literature regarding the biosafety lab at Fort Detrick remains relatively scarce, compared to the other cases selected for this study. Stakeholders in this project include the Army, and the local Fredrick residents. The Army clearly avoided including community perceptions, evidenced by approaching the risk assessment as a chore instead of a collaborative opportunity to develop a community relationship (NRC, 2011). Prior unreported LAIs validated negative community perceptions (NRC, 2010d; NRC, 2011).

Coeur d' Alene history suggests collaboratively bridging scientific evidence with community negative perceptions (Aiken, 1994; NRC, 2005). When the community recognized the hazards, the mining companies simply purchased pollution rights (NRC, 2005). Superfund designation provides resources for cleanup (NRC, 2005). The federal government won the lawsuit against the mining companies to

fund cleanup (Fifield, 2009). The critical assessment of the probabilistic model regarding remediating Coeur d' Alene suggest issues with models in all these cases (NRC, 2005, p. Appendix F).

The appendix authored by Crouch discusses the confusion between uncertainty and variability, an issue with many risk assessments even among experts. Crouch illuminates the assessment uses unjustified hypotheses, neglecting to provide data or plausible theories that the volume of material remediated is proportional to the load reduction from a given source and for a remedial action. Similar inconsistencies abound in the early assessments of NEIDL, and continued in NBAF (NRC, 2010; NRC, 2010b).

Dr. Crouch clearly quantified the discrepancies between the probabilistic model and reasonable logic. He questioned the validity of small probabilities regarding the remediation techniques based upon the contamination magnitude throughout the Coeur d' Alene basin, suggesting the model incorrectly assumed a constant contaminant decay rate, and therefore misrepresenting the total metal contamination. His expert assessment of the risk assessment suggests the agency overlooked critical indicators, used invalid assumptions, and invalid technical methods. Overall, he questioned the risk assessment validity, based upon contamination magnitude. Perceptions involved with assessing Coeur d' Alene contamination included overlooking significant issues from the outset. Crouch correctly points out the questionable potential cleanup results.

Coeur d'Alene, Fort Detrick, NBAF and DRMS risk assessments collectively support the social scientists' suggestions relative to including stakeholder perceptions

in assessments. Limiting risk assessment to incomplete technical analysis, inconsistent uncertainty treatment, without capturing and developing stakeholder perceptions is detrimental in several ways: poor communication, poor community relations, public suspicion and mistrust, and worse, the potential for a documented hazard to occur (Aiken, 1994; Botzen, Kunreuther, & Michel-Kerjan, 2014; Carignan, 2014; Delta Vision Blue Ribbon Panel, 2013).

4.4 Risk Perception Management (RPM) Plan

Risk Perception Management (RPM) involves expanding the current risk assessment and management processes to include the social science experts at the beginning of the iterative risk management process. Originating with the Red Book in 1983, the four-step process articulated at that time specified the separation of risk assessment and analysis from the risk management and decision-making, using defaults to suggest departures from data to account for the inherent uncertainty within risk analysis (NRC, 1983).

During the 30 years hence, the Red Book process has been evaluated and updated to include suggested improvements regarding transparency, data and process clarity, use of cumulative probability density functions instead of a singular probability, including technical improvements such as Monte Carlo and other analytical and subjective methods to assess risk and enable decision making (Bedford & Cooke, 2001; Davies J. C., 1993; Dooley, 2006; EPA , 2002; EPA, 2003; EPA, 1989; EPA, 1992; EPA, 2000).

These process improvements, while indeed valid and necessary as the complexity of the problems has evolved, stop short of suggesting deliberate, purposeful perception management. Decision science expertise and practice suggests including perception management into the project risk assessment practice and management enables optimal decision-making, particularly under uncertainty (Bedford & Cooke, 2001; Morgan, Henrion, & Small, 1990; Fischhoff & Kadvany, 2011). The process could potentially look similar to the flowchart in Figure 3.

A drawback of accounting for perceptions could lead to delays in project schedule as the risk assessment extends into understanding perceptions held by stakeholders and decision makers. The balance of including perceptions lies within perception management practice.

The concept of the RPM involves iteratively framing and reframing stakeholder perceptions, working through the risk register. Iteratively reframing exposes the underlying contributions to analysis paralysis, enabling optimal decisions (Hoch, Kunreuther, & Gunther, 2001; Morgan, Henrion, & Small, 1990). Hindsight enables evaluating each of these selected projects within the postulated updated framework to include the risk perceptions.

Alternatively, social scientists caution that persuasive effort could potentially steer a decision to positively influence a subset of stakeholders, to the detriment of other stakeholders (Fischhoff & Kadvany, 2011; Morgan, Henrion, & Small, 1990). They suggest avoiding this potential pitfall by including all stakeholders at the outset, thus thoroughly vetting perceptions and possible outcomes associated with those

perceptions in the decision-making process. NEIDL is the example of success (Jahnke, BU Today, 2014).

NEIDL and IPET reflect success with respect to an RPM. As risk communication improved, framing and reframing of issues associated with stakeholder perceptions enabled decision improvements by strengthening communication processes. Social experts suggest that as communication improves, perceptions are changed. Thus the communication can be tailored to achieve a desired perception and subsequent decision, which is the premise behind writing a persuasive paper in an undergraduate English course (Hoch, Kunreuther, & Gunther, 2001).

IPET served the public interest well, as evidenced by the reception of the comprehensive nine-volume report and final summary. Protection system evaluation relied upon communicating and understanding stakeholder perceptions as the assessment of the failed system unfolded. The IPET process was referenced as a model for the State of California to emulate, given the potential similar hazards in the California Delta (CALFED Independent Review Panel, 2008).

Unfortunately in the Delta, perception management processes overlooked conflicting constraints between water use and water conservation, contributing to deviation from original legislated goals, and aiding development of ancillary efforts, thus diluting potential comprehensive solutions to the ecological, environmental, infrastructural and conservational problems (California Legislature, 2005; MWD, 2011). The public developed a website providing a repository of the various conflicting reports regarding the Delta assessments and options (Delta Landowners,

2014). This research suggests the Delta remains unresolved until the Delta stakeholders come together to iteratively frame and reframe respective perceptions and communicate them comprehensively.

Also from a hindsight perspective, the deliberate inclusion of perception management into the NBAF and Fort Detrick risk analyses could have enabled those projects to successfully proceed. In addition to ignoring the independent reviewers' suggestions, the NBAF risk assessment lacked alignment between the risks perceived by the local community (NRC, 2010b; NRC, 2012). Conducting the risk assessment for the facility expansion at Fort Detrick as a chore, instead of approaching it as a collaborative effort within and between the local community and the federal government contributed to the overarching mistrust between the stakeholders (NRC, 2011).

Assessing improvements from the perspective of risk perception management as an element of the process remains a speculative exercise. Based upon decision science experts, decision-making improves when options and perspectives are framed and reframed, accounting for how risks are presented (Hoch, Kunreuther, & Gunther, 2001).

4.5 National Bio- and Agro-Defense Facility (NBAF)

The NBAF Final EIS (FEIS) discussed alternative sites and their relative merits regarding land use, infrastructure, air quality, noise, geology, water, biological and cultural resources, and socioeconomics, traffic, waste management, and health and safety (DHS, 2008). DHS reduced the assessment regarding FMDv release in the

FEIS to a minimal effort, briefly indicating FMDv release as a public concern; highlighting a LLNL report regarding economic impact of FMDv release; and suggesting an FMDv release would have no impact to hunting (DHS, 2008). Congressional records regarding assessing FMDv release compared the limited discussion in the EIS to comprehensive stakeholder concerns, suggesting disconnects between the EIS, DHS risk assessment process, and widely-held stakeholder concerns (111th Congress, 2009).

Prior to releasing NBAF construction funds, Congress mandated DHS provide an integrated risk assessment regarding safe facility operation, specifically addressing spread of FMDv and its associated economic impact in the event of a release (111th Congress, 2009). DHS delivered a site-specific risk assessment (SSRA) for review by a panel of NRC experts. The NRC reviewers commended DHS for including FMDv release via multiple potential pathways, responding to GAO's criticism regarding airborne FMDv release (NRC, 2010b).

The site-specific risk assessment contained comprehensive quantitative numbers, scenarios, and small probabilities, neglecting a comprehensive assessment regarding conducting FMDv work in Manhattan, Kansas (DHS, 2008; Signature Science LLC, 2010; NRC, 2010b). DHS estimated 70% probability of an infection resulting from an FMDv release over 50 years with an economic impact of \$9 to \$50 billion, although the SSRA characterized the risk as very low (Signature Science LLC, 2010). Considering the location in Kansas, DHS underestimated the probability of an FMDv release and its economic impact (NRC, 2010b). Overoptimistic scenarios resulted in underestimated risks (NRC, 2010b).

DHS used arbitrary and biased assumptions in the epidemiological, tornado and dispersion models, which experts had difficulty following and reproducing (NRC, 2010b). The NRC reviewers suggested the 2008 NRC assessment process, as well as the NEIDL risk assessment, as models for DHS regarding the NBAF assessment.

DHS modeling contained methodological flaws (NRC, 2010b). The NRC committee of experts was unable to establish the model input parameters to the software used to model animal disease spread. DHS cited limitations of the model regarding geography, subsequently indicating the model geographic area as a “hub of animal movement for the entire U.S.” (Signature Science LLC, 2010, p. 176). The SSRA discussed inapplicability of a network model due to the inability to obtain animal movement data from 10,000 animal facilities of five different types in seven states (Signature Science LLC, 2010).

Cited by the review committee, input parameter limitations and lack of modeling skills support public stakeholder concerns regarding underestimating an FMDv release and the subsequent potential economic impacts. The reviewers further cited concurrence with a parallel NRC review regarding DHS shortcomings with respect to agency risk analysis capabilities, aligning with the deficiencies in the SSRA (NRC, 2010b).

Following the SSRA, DHS published the uSSRA two years later, with similar deficiencies (NRC, 2012). A second time DHS underestimated the risk associated with FMDv release by assuming probabilistic independence within the scenarios (NRC, 2012). DHS reiterated the risk assessment, yet the outcome changed little,

with little input from stakeholders, noted by the second review committee (NRC, 2012).

The SSRA and uSSRA referenced consultations with local stakeholders regarding mitigation and culling procedures in the event of an FMDv outbreak (Signature Science LLC, 2010; Signature Science, LLC, 2012). The reviewers of both assessments cited shortfalls in mitigation planning efforts, suggesting DHS collaborate with local stakeholders to develop an appropriate process (NRC, 2010b; NRC, 2012). Stakeholders' concern regarding FMDv release and subsequent economic impact remains unaddressed, with little collaboration with DHS (Concerned Citizens, 2008). The SSRA and uSSRA refer repeatedly to collaboratively developing emergency protocols and mitigation plans within the community, although little evidence regarding plans materialized for review (NRC, 2010b; NRC, 2012).

Local community stakeholders express critical concern with NBAF progress, in light of NRC reviews of the SSRA and uSSRA (Concerned Citizens, 2008). Until January 2014, Congress withheld funding (111th Congress, 2009; U.S. House of Representatives, 2013; U.S. House of Representatives, 2014).

Kansas political stakeholders continually express enthusiasm regarding NBAF progress and benefits for Kansas (State of Kansas, 2009). Local and state elected leaders, in partnership with DHS, moved forward with construction, breaking ground in May 2013 (State of Kansas, 2009). DHS NBAF risk assessment process delivered the desired result, at double the cost, from \$500 million to almost \$1 billion

(Concerned Citizens, 2008; 111th Congress, 2009; U.S. House of Representatives, 2014).

Considering the 2008 NRC risk assessment model, NBAF risk assessment process failed the Kansas community stakeholders. Experts criticized the NBAF risk assessments, modeling methods, assumptions, and processes (NRC, 2010b; NRC, 2012). Experts criticized DHS capability and skills regarding risk analysis, citing agency shortcomings (NRC, 2010c). The critical risk assessment review informed the initial decision to withhold funding, although Congress eventually restored funding (111th Congress, 2009; U.S. House of Representatives, 2014). According to the congressional voting record, Congressman Rogers, chair of the House Appropriations Committee responsible for the federal budget, changed his vote against funding NBAF in June 2013 to restoring funding in January 2014.

The SSRA and uSSRA specified a Stakeholder Engagement Plan, although the assessment neglects to specify engagement activities (Signature Science LLC, 2010; Signature Science, LLC, 2012). Reviewers specifically suggested DHS collaborate with stakeholders (NRC, 2010b; NRC, 2012).

Against recommendations from federal and academic experts, DHS assessed the need to replace PIADC on the U.S. mainland, with the possibility of reintroducing FMDv into the food supply. The state of Kansas ignored capturing and including perception management into the NBAF risk assessment process (State of Kansas, 2009).

The evidence regarding NBAF perception changes is limited to the June 2013 and January 2014 congressional records. The research suggests the change to support

NBAF is politically-motivated, given the stakeholders in Kansas supporting NBAF construction are state and federal elected officials, and stakeholders opposing NBAF are local concerned citizens (State of Kansas, 2009; Concerned Citizens, 2008). Website comments from community stakeholders suggest the process was politically motivated (Concerned Citizens, 2008).

The gaps between NBAF stakeholders are wide. The evidence suggests experts indicated risk assessments fell short, federal officials questioned whether FMDv can be safely studied on the U.S. mainland, community stakeholders continue believing they were excluded from the process, and construction started.

The concept of an RPM involves collaboratively addressing stakeholder concerns and delivering an appropriate risk assessment. An RPM capturing community concerns could motivate DHS to adequately address the GAO question regarding whether FMDv research can be safely conducted on the U.S. mainland. A risk perception register capturing local stakeholders' perceptions and concerns, and iteratively assessing the risks and perceptions could potentially bridge evident gaps between opposing NBAF camps.

NBAF demonstrates the need for including stakeholder perceptions into the project risk assessment. Experts questioned technical merits of the NBAF risk assessments, citing significant duplicate deficiencies (NRC, 2010b; NRC, 2012). DHS assessed the question associated with FMDv technical research (DHS, 2008). Government and community stakeholders perceived a different, larger issue, questioning DHS capability to safely conduct FMDv research and prevent a release, and economic impact associated with U.S. losing its status as FMDv-free since 1929

(Concerned Citizens, 2008; 111th Congress, 2009; GAO, 2009). Stakeholders' perceptions of avoiding the question regarding FMDv release and associated damage contributed to mistrust, withholding construction funds, and slowing NBAF progress (111th Congress, 2009; Concerned Citizens, 2008; State of Kansas, 2009). Recent congressional support for NBAF supports the notion that the project is politically-motivated, enforcing community concerns (U.S. House of Representatives, 2014; Concerned Citizens, 2008).

Expert reviewers found several deficiencies in the NBAF risk assessment, supporting opposing stakeholders' perceptions and claims (NRC, 2010b; NRC, 2012). The reviewers documented a lack of available infectious disease experts and treatment facilities in the event of an FMDv outbreak. DHS provided small probabilities in tabular format experts found difficult to follow and interpret, citing tornadoes and earthquakes as the largest hazards (NRC, 2010b; NRC, 2012). These hazards fail to address stakeholder primary concerns of an FMDv release (GAO, 2009; Concerned Citizens, 2008). Subsequent assessments insufficiently reflected pathogen releases and impacts, including FMDv, fueling stakeholder concerns (NRC, 2012; Concerned Citizens, 2008).

DHS insufficient risk assessment expertise supports the misalignment between stakeholders and the agency from a technical as well as a process perspective (NRC, 2010c). DHS delivered substandard technical methods and analysis regarding dispersion associated with weather and seismic events, neglecting to address stakeholder concerns associated with FMDv release (Signature Science LLC, 2010; Signature Science, LLC, 2012; NRC, 2010b; NRC, 2012; Concerned Citizens, 2008).

Combining the 2008 risk assessment model with an RPM serves to iteratively include and address questions regarding FMDv release and associated economic impact. Development of a comprehensive risk register and associated stakeholder perceptions with each risk could improve the risk assessment by adequately addressing and responding to community concerns. Stakeholders currently perceive the NBAF is being pushed upon them with little recourse or voice in the public process (Concerned Citizens, 2008).

The NBAF SSRA and uSSRA produced mixed results, depending upon the reader's perspective. Political stakeholders continually express enthusiasm regarding NBAF progress and benefits for Kansas (State of Kansas, 2009). Local community stakeholders express critical concern with NBAF progress, in light of NRC reviews of the SSRA and uSSRA (Concerned Citizens, 2008). Local and state leaders, in partnership with DHS, move forward with construction (U.S. House of Representatives, 2014; State of Kansas, 2009). From an agency perspective, DHS NBAF risk assessment process delivered the desired result, at double the cost, however (111th Congress, 2009). NBAF construction moves forward.

From the NBAF skeptics' perspectives, the risk assessment process failed. Experts criticized the NBAF risk assessments, modeling methods, assumptions, and processes (NRC, 2010b; NRC, 2012). Further, experts criticized DHS capability and skills regarding risk analysis (NRC, 2010c). The risk assessment informed the initial decision to withhold funding, although Congress eventually restored funding (111th Congress, 2009; U.S. House of Representatives, 2014).

The SSRA and uSSRA specified a Stakeholder Engagement Plan, although little evidence exists regarding engagement activities. Congressman Rogers, chair of the House Appropriations Committee responsible for the federal budget, changed his vote against funding NBAF in June 2013 to restoring funding in January 2014, reflecting stakeholder engagement change (U.S. House of Representatives, 2013; U.S. House of Representatives, 2014).

Against recommendations from federal and academic experts, DHS assessed the need to replace PIADC on the U.S. mainland, with the possibility of reintroducing FMDv into the food supply (GAO, 2008). The state of Kansas ignored capturing and including perception management into the NBAF risk assessment process, evidenced from the state's website (State of Kansas, 2009). The evidence regarding perception changes is limited to the congressional efforts in June 2013 and January 2014, cited above. Although the evidence remains vague, the research suggests the change to support NBAF is politically-motivated. Stakeholders in the Kansas website supporting NBAF construction are state officials. The website opposing NBAF is limited to local citizens.

The value of the NBAF risk assessment process depends upon perspective. DHS valuation of the risk assessment process is questionable, given the duplicity between the SSRA and uSSRA. Website comments from community stakeholders suggest the process was politically motivated, articulating little value for the risk assessments (Concerned Citizens, 2008).

Theoretically, an RPM could serve to enlighten the politicians' views regarding safety and costs, as articulated by the congressman from New York in June

2013 (U.S. House of Representatives, 2013). Achieving agreement regarding perceptions associated with an FMDv release remains an idea, although GAO adequately provided evidence of the negative impacts (GAO, 2008; GAO, 2009). In hindsight, an RPM describing community concerns could motivate DHS to adequately address the question regarding whether FMDv research can be safely conducted on the U.S. mainland.

4.6 National Emerging Infectious Diseases Laboratories (NEIDL)

NEIDL demonstrated RPM theory in practice. Over time, the risk assessments evolved to provide stakeholders with confidence their concerns were being heard, understood, and evaluated, culminating in the CLC (Boston University Medical Campus, 2014). In addition to the technical aspects associated with BSL-4 laboratory operations, public concerns regarding a release were alleviated through establishment of the BRP and CLC, and transparent communication regarding the process progress (BU Press Release, 2014; Boston Bar Association, 2014). The assessment process improved, including stakeholder perceptions and communication to the extent reviewers suggested NBAF follow the NEIDL assessment methodology (NRC, 2010b).

Beginning with the original NIH grant award to BU, the NEIDL risk assessment process evolved over 11 years. Determining the efficacy of the risk assessment process for NEIDL therefore involves a time element. Although the process seems to have produced the desired result – the NEIDL was complete in 2011 – BSL-4 research faces the final approval hurdle by the Boston Public Health

Commission (Jahnke, BU Today, 2014). NIH changed risk assessment contractors throughout the process, leading to the conclusion NIH recognized the need for risk communication at the expense of contractors who did not.

The initial risk assessment deemed inadequate was conducted by RWDI West (NIH (RWDI West, Inc.), 2005). Each subsequent NRC review strongly repeatedly articulated the exclusion of prior recommendations, and the need to utilize the 2008 updated Red Book iterative assessment process (NRC, 2010; NRC, 2010a; NRC, 2011b). The critical NRC reports throughout the process leads to the conclusion the Tetra Tech team failed to prioritize an iterative, transparent, feedback process. The SFIER, delivered by Four Point Associates, meets NEPA requirements, enabling the approval process toward BSL-4 research to move forward (Four Point Associates, Inc., 2013; Jahnke, 2013; Jahnke, BU Today, 2014).

Determining process efficacy of the NEIDL risk assessment includes studying the risk communication methods and process, including an RPM. NIH and BU demonstrate the theory of an RPM, without calling it out specifically. Recognizing the need to communicate risks effectively, responsively, and completely, NIH developed critical elements of the theory, starting with the sources of risk hazards shown prior in Figure 2.

Following expert and community input, NIH iteratively developed risk assessments using open, transparent communication with NRC and the public (NIH, 2008; NRC, 2008d; NRC, 2010; NRC, 2010a; NRC, 2011b). The NEIDL website shows the commitment to open engagement with the community. The open, critical and iterative review of interim risk assessments throughout the process demonstrates

NIH perception management. NIH incorporation of all NRC recommendations into the final assessment demonstrates a comprehensive feedback loop.

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Studying the NEIDL risk assessment process includes unraveling complex risk communication methods and processes utilized within the court system and public forums. NIH and BU demonstrate the theory of an RPM, without calling it out specifically. Recognizing the need to communicate risks effectively, responsively,

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NIH established the BRP as a resource for the risk assessment, although the initial interaction fell short of this goal (NIH Blue Ribbon Panel, 2008; NIH, 2009). Following expert and community input, the BRP and the risk assessment contractor iteratively developed risk assessments using open, transparent communication with NRC reviewers and the public, including public (mis)perceptions associated with establishing a BSL-4 laboratory in an urban area (NRC, 2010; NRC, 2010a; NRC, 2011b).

The NEIDL website is evidence of commitment to open engagement with the community. The open, critical and iterative review of interim risk assessments throughout the process demonstrates NIH perception management. NIH incorporation of all NRC recommendations into the final assessment demonstrates a comprehensive feedback loop.

4.7 Fort Detrick

The proposed model provides protocol framework for conducting, developing and delivering risk analyses for these large projects could turn inconsistent risk analysis performance into credible, sustainable, repeatable risk assessment efforts across all agencies. Involving all the stakeholders from the start, clearly articulating the problem the assessment should address, iteratively capturing the perceptions held

by stakeholders to generate an RPM, and overall iteration of the risk analysis process for making choices would serve the agencies, and ultimately, the public good.

Risk assessment process efficacy regarding Fort Detrick high-containment laboratory facilities involves evaluating the relationship between Army leadership and the local community. The community continues to exhibit skepticism regarding facility safety (Carignan, 2014).

The facility is under construction, scheduled for completion in May 2015 due to a welding fire in 2013 (Carignan, 2014). Within this research, risk assessment process efficacy involves more than constructing a laboratory facility, however. Using the 2008 updated Red Book process as a starting point, this research suggests process efficacy includes public perceptions associated with high-risk projects, and developing a consistent risk assessment methodology within federal agencies to account for public perceptions.

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Risk assessment process value regarding Fort Detrick high-containment laboratory facilities involves evaluating the relationship between Army leadership and the local community. The community continues to exhibit skepticism regarding

facility safety (Carignan, 2014). The facility is currently under construction, although delayed due to a welding fire in August 2013 (Carignan, 2014).

The Fort Detrick risk assessment process includes neglecting public perceptions associated with high-risk projects. The little available literature regarding insufficient risk assessment depth, overlooking community involvement, suggests the Army develop consistent risk assessment methodology to account for public perceptions (NRC, 2011).

4.8 Interagency Protection Evaluation Taskforce (IPET)

IPET developed risk assessments regarding five areas of the hurricane protection system: pre-Katrina protection system design; storm surge and waves, and protection system performance during the storm; societal consequences of the storm; and future risks to the New Orleans area (NRC, 2009). The IPET assessment process advanced risk assessment practice regarding predicting hurricane surge and wave effects by incorporating storm motion, intensity, size and barometric pressure as parameters in addition to the Saffir-Simpson 1 to 5 hurricane strength scale (USACE, 2014). According to the IPET assessment, hurricane risk reduction planning has advanced to include size, strength, motion and track, which affect storm surge.

The IPET risk assessment exemplifies practicing iteratively developing a comprehensive RPM with all stakeholders. Assessing perceptions associated with a hazard is a critical component of an RPM. Iterating the assessment is also a component suggested in this research and also by the NRC (NRC, 2008). Through the course of development, IPET iteratively considered public perceptions associated

with living behind protection levees because New Orleans residential and infrastructure development advanced without equivalent protection system advances (USACE IPET, 2006).

4.9 Pre-Katrina protection system design

The IPET comprehensive assessment regarding the pre-Katrina protection system design indicated the system “did not perform as a system...a system in name only” (USACE IPET, 2006), page I-3. The NRC review committee repeatedly criticized IPET for neglecting to evaluate the protection system as a comprehensive system (NRC, 2006; NRC, 2006b; NRC, 2006c). System design and construction evolved over 50-plus years, with multiple stakeholders providing varying resources, materials, and design and construction methods (USACE IPET, 2006). During that time, levees had subsided (eroded), varying levee heights were approved, and New Orleans residents established a false sense of security in a less-than-capable system.

Katrina arrived, validating to residents of New Orleans the weakest link of a “system” breaks the system. Katrina exposed multiple weak links, with catastrophic results. The storm exceeded design criteria. Protection components contained inconsistent protection levels and construction materials. City planners neglected to develop evacuation and assistance protocols for a city as vulnerable as New Orleans. Everyone in New Orleans recognized the city sits lower than sea level and is surrounded by water, increasing the vulnerability, according to IPET. This lack of planning acutely impacted the city’s large poor elderly population living in the lowest points of the “bowl” (USACE IPET, 2006).

4.10 Storm Surge and Waves

Hurricane Katrina hydraulic forces and water levels exceeded the system design criteria. Surge levels were five or six feet higher than the design levels for the southern and eastern sides of the system. Wave heights approximated the design criteria, with the exception of Plaquemines Parish where the waves were significantly higher. Wave periods extended three times longer than the design criteria, leading to levee overtopping. The design criteria assumed 1-foot-high waves. Katrina delivered 4-foot-high waves.

The NRC review committee repeatedly commented IPET should define the Standard Project Hurricane (NRC, 2006; NRC, 2006b). IPET indicated the hurricane protection system used four different standard project hurricanes (SPH) (USACE IPET, 2006). Inconsistent storm characterization guided protection system development, preventing IPET settling onto one SPH model. IPET extended hurricane modeling incorporating storm motion, intensity, size and barometric pressure as parameters, going beyond the Saffir-Simpson Scale of one parameter (wind strength) (USACE IPET, 2006).

4.11 Protection system performance during the storm

Katrina left 50 major breaches in her wake (USACE IPET, 2006). According to IPET, four of these were due to foundation gaps forming between the levee and adjacent soil. The remaining 46 were due to overtopping waves and erosion from the wave speeds (USACE IPET, 2006). IPET noted the development of gaps as a failure mechanism was excluded from the original structure design.

Eighty percent of the New Orleans metropolitan area flooded due to breaches (2/3), and overtopping (1/3). Seventy percent of the flooding in Orleans East Bank was traced to three foundation failures in that area, according to IPET.

Breaches occurred due to inconsistent transitions between protection types across the system (USACE IPET, 2006). Breach vulnerabilities resulted from transitions under different management operations, incomplete authorized construction, and levee/floodwall city service openings (USACE IPET, 2006).

4.12 Societal consequences of the storm

Human casualties were over 1500. Flood depth correlated to the lowest parts of the city, where most poor, elderly and disabled citizens resided, thus these groups sustained the largest impact (USACE IPET, 2006). IPET determined residents unable to quickly evacuate are at highest risk.

Katrina damage exceeded \$20 billion. Residences bore \$16 billion of this figure, commercial interests \$2.4 billion, and infrastructure \$6 to \$6.7 billion, with \$2.8 billion of infrastructure to the hurricane protection system (USACE IPET, 2006).

4.13 Future risks

The NRC committee repeatedly suggested IPET develop comprehensive GIS and geodetic flood inundation maps (NRC, 2006; NRC, 2006b; NRC, 2006c). IPET found inconsistent water level reporting due to subsidence over time, thus changing the sea level datums necessary to develop maps, resulting in map delivery delay as part of the Risk Assessment – Volume VIII (USACE IPET, 2006). The review committee suggested IPET provide further discussion using the maps regarding risk

implications across the region (NRC, 2009). The committee further suggested IPET collaborate with other agencies regarding inundation map development to improve consistency, and enable improving understanding future vulnerabilities to enable relocation and restoration decision-making.

The NRC noted IPET advanced the practice of assessing regional risks associated with hurricanes (NRC, 2008c; NRC, 2009). IPET developed a novel method of hurricane characterization and inundation predictability (USACE, 2014). In addition to technical advanced, IPET considered citizens' perceptions associated with living behind levees, below sea level (USACE, 2014; NRC, 2009). IPET further advanced preparation planning to assist metropolitan areas associated with reconstruction, levee restoration, and resettlement (NRC, 2009).

Katrina elevated comprehensive public perspective regarding risks of living behind levees, raising the priority and value of storm characteristics within levee design and construction (NRC, 2009). The resulting comprehensive risk assessment provides guidance to USACE and New Orleans-area stakeholders regarding rebuilding the protection system, resettling residential areas, and returning commercial opportunities to pre-Katrina levels (USACE, 2014).

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The IPET risk assessment exemplifies practicing iteratively developing a comprehensive RPM with all stakeholders. Assessing perceptions associated with a hazard is a critical component of an RPM. Iterating the assessment is also a component suggested in this research and also by the NRC (NRC, 2008). Through the course of development, IPET iteratively considered public perceptions associated with living behind protection levees because New Orleans residential and infrastructure development advanced without equivalent protection system advances (USACE IPET, 2006).

4.14 Delta Risk Management Strategy (DRMS)

The DRMS decisions remain open questions. Delta management stakeholders continue struggling with co-equal goals of water consumption and ecological sustainability (NRC, 2011; NRC, 2012a). Delta construction of conveyance systems continues (Delta Landowners, 2014). The Delta remains a disjointed effort among stakeholders with various perceptions misaligned toward closing risk assessment gaps (DWR, 2013; Delta Vision Blue Ribbon Panel, 2013; Delta Landowners, 2014).

The research suggests URS and DWR recognized Delta political sensitivity among stakeholders, choosing to limit the risk deliverable to the technical aspects of the levee infrastructure (DWR, 2009; DWR, 2011; DWR, 2013). The lack of Delta management collaboration, while much needed, and indeed suggested by the NRC in

2008 for conducting comprehensive risk assessments, has yet to occur (Lund J. , et al., 2008; NRC, 2012a).

In addition to the recommended collaboration, the DRMS effort could benefit from incorporating social science risk communication and risk perception management including an RPM, to provide a comprehensive management plan. Originated as a response to Katrina's devastation in New Orleans, the Delta management effort, including DRMS and the other authorized efforts, could benefit from a comprehensive risk communication plan similar to IPET. Indeed, the NRC suggested Delta stakeholders use the USACE IPET effort regarding the New Orleans hurricane protection system as a model for assessing water sustainability and consumption management and associated levee risk management decisions (NRC, 2012a).

Utilizing the NRC 2008 iterative risk assessment model as the starting point, this research focuses on the DRMS levee risk assessment from the perspective of adding value to the stakeholders through inclusion and development of a risk perception management plan into the risk assessment for making decisions, including whether the assessment provides a reasonable value for the stakeholders. As shown in Figure 3, this particular model is an extension and expansion of the original 1983 Red Book model and its subsequent 2008 updated model (NRC, 1983; NRC, 2008).

4.15 Coeur d' Alene

Coeur d'Alene represents the difficulties managing the spectrum of perceptions. EPA's assessment regarding remediation indicated possible restoration is achievable

(NRC, 2005). According to Crouch, a dissenting reviewer of the EPA Coeur d'Alene remediation assessment, the plan lacked a proven risk assessment process (NRC, 2005). His critical comments reflect EPA's evolution away from providing transparent risk characterization. For example, EPA published a risk characterization process documenting comprehensive transparency, clarity, consistency and reasonableness (TCCR) (EPA, 2000). EPA published guidance regarding superfund site assessments, environmental assessments, and cumulative risk assessments (EPA, 2003; EPA, 1989; EPA, 1992). Crouch argued the probabilistic model regarding Coeur d'Alene remediation restoration documented unreliable risk assessments which could be independently validated; assumed questionable hypotheses and distribution shapes; leading to an incorrect analysis (NRC, 2005).

Edmund A. C. Crouch, PhD, describes issues with the probabilistic model (TPM) for estimating metal loading and effectiveness of the remedial action in Appendix F of the Coeur d'Alene superfund document (NRC, 2005). Dr. Crouch specifically questions the TPM author's assumption of the variability and uncertainty distributions as lognormal distributions. He explains the TPM author's confused uncertainty with time variation. Dr. Crouch further indicates uncovering typographical errors in the analytical equations. He specifically articulates four deficiencies within the remediation analysis: 1. the analysis depends upon an untested hypothesis; 2. Issues with the treatment of time variation; 3. Undocumented, nonreproducible, and un-validated parameters and their values; 4. Incorrect probabilistic analysis.

Regarding the unjustified hypotheses in the analyses, Crouch indicates the author neglected providing data or plausible theories regarding the relationship between remediated material volume and source material volume for a specific remedial effort. The author postulated the volume of material remediated is proportional to the load reduction from a given source and for a remedial action without providing data or potential theories supporting this suggested relationship.

Crouch suggests the TPM authors incorrectly treated value and time variance following a remediation by assuming a constant decay rate for all times and all remediation scenarios. The TPM introduced a quantity called relative loading potential (RLP) defined as the leaching rate of metal from contaminated source material. Dr. Crouch suggested the assumption of a constant decay rate misrepresented the total mass of metal available for leaching. He indicated a constant decay rate left little room for a variable decay rate dependent upon the quantity of available leachable metal. TPM authors indicated a constant the decay rate of the annual average loading for all remediation processes across a variety of remediation methods, including no remediation.

Dr. Crouch quantified the discrepancies between the TPM and reasonable logic clearly. He articulated the small numbers provided by the TPM and questioned the validity of those values through references to the effective mass of the contaminated material available for leaching pre and post remediation, along with the respective change mass.

Coeur d' Alene lacked a technically valid risk assessment process (NRC, 2005). Critical NRC comments reflect EPA's evolution away from providing transparent risk

characterization (EPA, 2000; NRC, 2005). For example, EPA issued the risk characterization process documenting comprehensive transparency, clarity, consistency and reasonableness (EPA, 2000). Coeur d' Alene demonstrates the agency shift toward unreliable risk assessments which cannot be independently validated (NRC, 2005).

4.16 Going Forward

Issues in modern risk assessment cross many engineering disciplines (Crump, 2003; Harris, 1990; Machina, 1990; McClellan & North, 1994; Suter, 2006). Failure to utilize the updated NRC risk assessment methodology leads to a lack of transparency, clarity, consistency and reasonable results (EPA, 2000). Neglecting stakeholder perceptions and communication considerations widen gaps between opposing camps associated with complex projects.

Science and decisions often misalign to meet the epistemic needs within decision-making. Using the 2008 process as a framework for risk analysis, in an iterative fashion, with all stakeholders, and extending the analysis to iteratively account for risk perception including an RPM, increases risk assessment value from the outset. Increasing value through capturing stakeholder perceptions associated with the hazards in early stages of risk assessment contributes to reducing analysis paralysis, potentially improving decision-making (Hoch, Kunreuther, & Gunther, 2001).

Risk assessment iterations incorporating reviewer recommendations for each case did not always result in improved risk assessments. Fort Detrick continually

cultivated mistrust with community stakeholders because each assessment neglected to include prior reviewer recommendations, limited community involvement and input, and the contractor conducting the assessment viewed the process as a hurdle to overcome instead of a community collaboration (NRC, 2010d; NRC, 2011; NRC, 2011c). The DRMS analysis remains incomplete, ultimately becoming a political hurdle regarding a scarce resource instead of an assessment of Delta levee system health and fragility (CALFED Independent Review Panel, 2008; MWD, 2011). The NEIDL analysis improved to such an extent that it was held up as a model for IPET and NBAF (NRC, 2010b; NRC, 2006b). Coeur d'Alene lessons involve comprehensively assessing damage after contamination occurred. As Crouch critically points out, community stakeholders deserve accurate assessments regarding futility of mitigation efforts (NRC, 2005). Some experts, such as Crouch, argue that Coeur d'Alene contamination remains irreparable, suggesting scientists learn from contamination evidence as it appears instead of years afterward.

Chapter 5: Risk Communication and Stakeholder Management

Project management practice suggests developing a communication plan utilized throughout the project lifecycle. According to social science experts, the majority of human communication involves nonverbal components, with verbal communication limited to seven percent of the total communication pipeline (Daniels, Kettl, & Kunreuther, 2006; Fischhoff & Kadvany, 2011). Evidence in these cases suggest risk engineers consider effectively communicating risk information. The cases presented here suggest an integrated, multi-skilled, expanded risk assessment process beyond estimating event frequencies and calculating probabilities. This research suggests engineers incorporate social science processes regarding communicating technical information into risk assessments; become increasingly cognizant of collaborating with social experts regarding communication plan development; and thus facilitate improvements in risk assessment stakeholder management leading to potential project performance improvements.

5.1 Risk Communication Principles and Practices

The cases suggest increasing awareness of nonverbal communication components during risk communication plan development, connecting communication plans to the risk register, and thus increasing awareness regarding human tendencies associated with risk information presentation (Fischhoff & Kadvany, 2011; Bureau of Reclamation, 2011; Botzen, Kunreuther, & Michel-Kerjan, 2014; Morgan, Henrion, & Small, 1990; RAE, 2003). Independent reviewers associated with each case presented in this research suggested using social expertise

in communication plan development and dissemination (CALFED Independent Review Panel, 2008; NRC, 2010a; NRC, 2009; NRC, 2005; NRC, 2010).

Experts suggest good communication practice involves iterative, inclusive communication (Hoch, Kunreuther, & Gunther, 2001; NRC, 2008). As the risk assessment is developed and iterated, the communication plans also evolve into comprehensive communication updates regarding project risks, mitigation alternatives, and decisions as the project progresses. NEIDL demonstrated inclusive iterative communication evolution only after the BRP was formed and assigned to provide guidance to NIH. IPET iterated the plans from the outset and throughout the levee assessment process. The remaining four cases demonstrated lack of iterative communication, and the resulting associated damage to community relationships.

Experts suggest engineers carefully consider presenting probabilities and associated uncertainties (Kleindorfer, Kunreuther, & Schoemaker, 1993). According to social science experts, small numbers or probabilities tend to cloud human cognitive abilities, reducing our limited capability to understand and perceive numbers, percentages and ratios less than one (Hoch, Kunreuther, & Gunther, 2001). Consulting with social experts informs risk communication plans for engineers assessing low-frequency, high-impact risks.

Experts further suggest using audience-appropriate, practical language, providing a balanced, comprehensive response to each concern or groups of concerns stakeholders hold (EPA, 2000; Daniels, Kettl, & Kunreuther, 2006; NRC, 2012; NRC, 2009). Social experts collaborating with engineers guiding language, tone, and

assessment technical information serves to inform stakeholders, leading to improved decisions.

5.2 Case Risk Communication

The cases demonstrate the spectrum of risk communication practice. NIH recognized stakeholders needed to feel safe with infectious diseases nearby, changing NEIDL communication from defensive in the courts to collaborative within the community. The IPET team developed communication designed to increase awareness relative to levee fragility and system sustainability, which sometimes instead cultivated stakeholder mistrust and resistance (NRC, 2006c; NRC, 2009). NBAF and Fort Detrick project staff neglected to include appropriate communication practice, resulting in resentful stakeholder communities (NRC, 2011; NRC, 2012; Concerned Citizens, 2008). DRMS communication succumbed to political pulls between competing interests, evidenced by the critical review indicating overlooking environmental and water provision goals. Coeur d' Alene communication involves critical expert review of questionable technical assessment processes, suggesting modern stakeholders' resignation to contamination permanence (NRC, 2005).

5.2.1 National Emerging Infectious Diseases Laboratories (NEIDL)

Communication plans associated with the NEIDL project changed from legal antagonistic responsiveness into collaborative community public relations efforts. The legal communication has been discussed prior in Chapter 3:. The BRP suggested NIH change its communication process through a specific frequency of open forums;

categorically capturing and responding to stakeholder concerns; and incorporating expert suggestions into the risk assessment development and review process.

Although lacking a risk communication plan at the outset, NIH recognized providing transparent, clear, communication as a critical component of facility success. Establishing the Community Liaison Committee (CLC) in 2006 contributed to the successful completion of the facility, achieving endorsement of the risk assessments by independent expert reviewers, the courts, and ultimately the local community (BU Press Release, 2014). The evolution of NEIDL risk communication serves as a model for other projects.

NEIDL risk assessment iterations demonstrate suggested stakeholder management communication process improvements. The NEIDL case exemplifies project communication planning concepts, including the concept of an RPM associated with stakeholder perception connected with communication management. Including communication plans into the RPM concept involves iteratively responding to perceptions associated with stakeholder concerns assigned to each risk. The NEIDL risk assessment process became a model suggested to DHS for the NBAF facility in Kansas.

5.2.2 Interagency Performance Evaluation Taskforce (IPET)

The IPET team employed a risk communication plan to capture stakeholder perspectives and concerns. Although levee issues involved multiple technical disciplines, and experts from a wide variety of technical backgrounds, including risk communication principles resulted in a comprehensive risk assessment which

advanced levee construction and hurricane protection system risk assessment methodology (NRC, 2008c). These expert reviewers noted the comprehensive styles and efforts demonstrated by the IPET team. The IPET case demonstrates stakeholder engagement connections between stakeholder perceptions and communication planning through an RPM concept associated with stakeholder perception and communication management. Subsequently, IPET became an example for DRMS levee evaluation (CALFED Independent Review Panel, 2008; CALFED Independent Review Panel, 2007).

5.2.3 *National Bio- and Agro-Defense Facility (NBAF)*

The NBAF SSRA relied heavily on providing probability tables containing small numbers in decimal formats to show risk event probabilities (Signature Science LLC, 2010; Signature Science, LLC, 2012). Small probabilities reflect incomplete communication plans, previously discussed as a source of confusion for decision makers (Kleindorfer, Kunreuther, & Schoemaker, 1993). This communication gap contributed to the duplicity of the deficiencies articulated by two independent review committees, further reinforcing congressional and public skepticism (NRC, 2010b; NRC, 2012). Expert reviewers suggested DHS and stakeholders collaboratively develop the risk assessment to include stakeholders' concerns regarding conducting infectious disease research near susceptible animal populations, instead of simply providing tables of small probabilities and numbers inconceivable. The NBAF project combined several risk assessment process communication issues: ignoring

communication presentation effects; neglecting to respond to the technical deficiencies described by expert reviewers; and lacking stakeholder involvement.

5.2.4 *Fort Detrick*

The Fort Detrick assessment reflected incomplete communication regarding risks associated with potential lab-acquired infections (LAIs), as had occurred in the past at Fort Detrick, thus overlooking foreseeable problems and extending into incomplete risk characterization and insufficient communication with resident stakeholders. Expert reviewers of the Fort Detrick assessment suggested the Army iteratively develop risk assessments, including proven communication practices (NRC, 2011; NRC, 2011c).

The Army instead delivered an incomplete risk assessment work plan from which experts were unable to glean useful practical assessment value, noting the Army's reluctance to clearly communicate with public stakeholders, thus widening the communication gap between communication stakeholders and Army leadership at Fort Detrick (NRC, 2011). The analysts conducting the risk assessments missed an opportunity to collaboratively align with the community, and thus potentially improve Army relationships locally.

Public stakeholders remained unconvinced of the Army's capabilities to construct a safe infectious disease laboratory. Subsequently, the Army moved forward, changing the project plan from constructing a new facility to refurbishing an existing facility (NRC, 2011c).

5.2.5 *Delta Risk Management Strategy (DRMS)*

The issues involving managing, refurbishing, retaining, and restoring the levee system are notably complex. A complex array of stakeholders claims the levee system, further complicating the risk communication processes. The DRMS risk assessment deviated into this complex political foray equally focused on water consumption and ecological management, thereby exacerbating system frailties and the communication regarding the frailties to the stakeholders. DRMS serves as an outstanding example of the policy process disintegrating, changing a technical risk assessment into a political battle over competing interests.

Recall from Chapter 3: the impetus for the Delta assessment was the levee system damage in New Orleans after Hurricane Katrina. Focusing the risk assessment process toward preventing a Delta-version of Hurricane Katrina, California stakeholders might have reached a decision regarding levee attention. As the assessment process progressed CALFED reviewers repeatedly communicated ecosystem and ecological management as higher priority than assessing levee system stability.

The DRMS case demonstrates progression from cogent risk assessment plans into politicized risk assessment efforts disconnected from the original risk assessment intent. The DRMS assessment remains a disjointed effort of managing a limited resource (water) with a propensity of failure from multiple modes, before a resolution or agreement can be reached.

5.2.6 *Coeur d' Alene*

Coeur d' Alene bears the effects of earning a profit while irreparably damaging the ecological system of the Coeur d' Alene river and its environment when the mining companies dumped mining waste into streams, and smelters belched noxious particulates across the hills and into the valleys. Communication regarding environmental remediation assessment of Coeur d' Alene suggests incompetent technical risk assessment, coupled with resignation that remediation is impossible (NRC, 2005). Including Coeur d' Alene in this research regarding stakeholder perception management and communication via an RPM suggests increasing risk assessment value through recognizing risks associated with an industry practice, capturing stakeholder concerns associated with the practice, and collaboratively responding to those concerns using the risk register.

Neglecting these novel practices reflects analogies to the tobacco industry, the hydraulic fracking industry, coal-fired power plant emissions, and other modern environmentally sensitive industries demonstrating questionable evidence about which community stakeholders can do little. Coeur d' Alene serves as historical evidence regarding deliberately ignoring and overlooking hazardous outcomes and subsequent damages in the face of opposing communication practices.

Chapter 6: Conclusions

Engineers solve technical problems, provide technical solutions, and interpret technical information for stakeholders' benefit to aid decision-making. The literature indicates, and these cases demonstrate, stakeholder decision-making reflects social

elements extending beyond technical information. Stakeholder decision-making depends upon technical information appropriately connected with stakeholder perceptions associated within the risk register. This research submits capturing stakeholders' perceptions with each risk, and then iteratively developing appropriate communication plans. Our proposed process leads to improved project communication plans, improved stakeholder engagement, and successful project completion, demonstrated by NEIDL and IPET.

These cases provide examples of projects initiated from a controversial position, such as IPET and NBAF. Based upon agency experts withholding from the public information regarding a prior pathogen release, NEIDL and Fort Detrick began from an adversarial community position, thus contributing to negative community perceptions and distrust at the outset. Through collaborative community efforts NEIDL demonstrated successful implementation of the RPM by engaging experts to help connect risk assessment and communication processes through capturing stakeholder perceptions. Conversely, the agency responsible for Fort Detrick's new BSL-4 facility ignored community perceptions, avoided communication, and moved forward with an expansion without regard to local residents' concerns. In this respect, Fort Detrick represents a subpar example, while NEIDL became a model experts subsequently suggested for NBAF.

NBAF represents a subpar stakeholder engagement process. The technical risk assessment experts avoided addressing the potential of an FMDv release, a primary concern held by community stakeholders, and mandated by Congress in 2009. Instead, the technical risk assessment provided small numbers, distinct probabilities,

and myriads of technical information useful for experts, thus providing questionable value for community stakeholders and elected officials. Ultimately ignoring the mandate, federal and state leadership points to economic benefits and potential jobs, and the project moves forward without an appropriate risk assessment. Experts agree the technical risk assessment is deficient. Community stakeholders continue to question the potential of an FMDv release.

Our six cases demonstrate the importance of stakeholder understanding and acceptance of a clear risk communication plan. This was demonstrated in the NEIDL project by development of the BRP, leading into the CLC, and expansion of the laboratory functionality into open houses, educational opportunities and facility tours connected into community relations processes; and in the IPET project by developing stakeholder communication plans at the outset of the project utilized throughout the levee system assessment project to maintain and improve resident understanding of the hazards associated with living below sea level in a storm-prone environment.

The opposite was demonstrated in Coeur d'Alene by companies and federal agencies ignoring evidence of health and environmental damage. At Coeur d'Alene the damage had been permitted through the purchasing of environmental pollution rights. At Ft. Derrick the damage occurred by expanding the laboratory without responding to stakeholder concerns. Stakeholder understanding of the communication plan builds trust between government agencies and community stakeholders, cultivates collaborative community partnerships, moving projects forward as can be seen in the Boston authorities' approval of the NEIDL and the collaborative nature of the New Orleans rebuilding.

Our cases demonstrate the spectrum of project stakeholder engagement through project management communication plan iterations connecting stakeholder perception through an iterative risk assessment. The RPM concept suggests improving risks assessments through including stakeholder perception and communication plans using the risk register.

6.1 Successful Communication and Perception Planning: NEIDL and IPET

Characteristics of successful comprehensive communication planning include collaborative conversations to gather stakeholder perceptions; comprehensive community stakeholder involvement insuring representation from all stakeholders; clear articulation regarding risks and mitigation efforts using audience-appropriate language; providing progressive iterations via public forums throughout the risk assessment process to inform stakeholders and gather their feedback throughout the process; experts providing clear connections between the risk(s) and decision(s) at hand throughout the process, including audience-appropriate language documenting risk assessment changes and decisions associated with each iteration; agency responses reflect each stakeholder concern. These elements, developed collaboratively between technical and social experts, reflect sharing ideas, concerns and progress exchanged to achieve stakeholder understanding, thus improving stakeholder engagement and risk communication.

NEIDL and IPET demonstrated successfully connecting the communication plan to the risk assessment through stakeholder perceptions. Risk assessment process

similarities within both projects resulted in improved project stakeholder engagement and acceptance, and increased risk assessment value.

6.1.1 *NEIDL*

NIEDL demonstrated community collaboration when community groups separated via lawsuits ultimately reconnected through the BRP and CLC open stakeholder forums. NIH charged the BRP with responding to each concern raised by stakeholders via seven open forums during which several thousand concerns were captured and categorized. NIH captured all stakeholder comments during the forums and generated responses for each. NRC expert reviews discussed NIH's ability to capture and respond to each stakeholder concern. NRC experts repeatedly noted risk assessment improvements with each iteration, commenting on how the final risk assessment contained all NRC technical improvement recommendations, in addition to stakeholder perceptions. The final review further elaborated regarding NIH responsiveness to community perceptions, indicating the comprehensive communication and perception management improvements, and increased risk assessment value, enabling stakeholder decision-making. NRC experts commended NIH deliberate inclusion of perception management and communication planning. As NIH iteratively included perceptions, and responded to stakeholder concerns, public perceptions evolved from a fearful position fighting against the laboratory into an informed position, supporting the laboratory opening and approvals.

BRP recommendations and activities provided to NIH throughout the NEIDL project process informed the CLC and community public relations processes. NIH developed a comprehensive communication plan, including conducting open houses and educational tours designed to appeal to all ages and understanding levels. The communication plan evolved into a public relations plan, complete with CLC input and approval, leading to community acceptance of laboratory research opportunities.

Beginning with the BRP, evolving into the CLC; developing public outreach and educational communication elements, including opening the laboratory to the public; these components demonstrate NIH progressive communication and stakeholder perception management practices. The BRP actively encouraged NIH to capture stakeholders' perceptions throughout the risk assessment process. Expert reviewers throughout the process noted agency responsiveness to community concerns. The agency comprehensively addressed every comment and concern, to the fullest extent. Experts suggested DHS use the NEIDL risk assessment process as that agency began developing the NBAF risk assessment.

Currently the NEIDL project is approaching full licensure of BSL-4 research, earning community support for the Boston authorities to approve licensing. Beginning from a position of mistrust, NIH and BU collectively increased stakeholder risk assessment value, leading to increased laboratory value within the community. The magnitude and relationship between these pieces remains an opportunity for further research into the novel notion of improved stakeholder engagement through the risk engineering process.

6.1.2 *IPET*

From the outset, the IPET team hurricane protection system assessment around New Orleans was developed as a community collaborative conversation. The final review of the risk assessment noted the team's capture and response to all stakeholder concerns and comments received during the iterative process. The final risk assessment and subsequent expert review noted community residents' perceptions changed as residents began to appreciate they live below sea level and the implications associated with that risk.

Throughout the IPET assessment process, healthy respect for the levee system and for storm potential replaced stakeholders' false sense of security. This perception change was noted in the final risk assessment and subsequent expert reviews. Facilitating these systemic perception changes, the IPET team developed continuous, transparent, clear communication plans throughout the levee assessment process.

IPET demonstrated progressive communication and perception practices by designing the risk assessment to capture and include stakeholder perceptions associated with a false sense of public security. As the IPET team articulated the risks hazards associated with living behind levees, the team's communication plans iteratively captured and responded to stakeholder perception changes, and enabled residents to broaden their understanding regarding choosing to live in a hazard-prone zone behind antiquated levees. The IPET process and report became the recommended standard for assessing the California Delta levee system in the DRMS project.

As the IPET team's risk assessment managed their communication processes, community perceptions regarding local hazards evolved into understanding the risks associated with the levee system. Stakeholder engagement improved as communication plans developed, improved and included all stakeholders, through the risk register and communication plans. Although arduous throughout the process, the value of the New Orleans levee system assessment increased, demonstrated by the advancements in hurricane prediction technology and stakeholder perception management processes for large metropolitan hazard-prone areas.

6.2 Unsuccessful Communication and Perception Planning: Fort Detrick, NBAF and DRMS

Unsuccessful communication and perception planning reflects concepts opposite of success: independent, disconnected efforts; little or no collaborative communication or collaboration regarding the assessment process; nonresponsive to stakeholder concerns; overlooking or ignoring stakeholder perceptions associated with risk(s); lack of communication planning regarding high-impact risk(s); few progressive practices regarding stakeholder engagement or communication planning included in the risk assessment design process. Although different from traditional measures of project success or failure, poor communication and stakeholder perception management reflect low risk assessment value for decision-making.

6.2.1 *Ft. Detrick*

NRC experts reviewed the risk assessment work plan, noting the lack of community communication. Expert reviewers expressed concern regarding the lack of responses to community concerns regarding laboratory safety and reporting processes, given past history of LAIs at that facility. Although the Army conducted open public forums and received comments, NRC experts noted the lack of documentation of the comments and lack of response planning in an effort to collaborate with the local community. Experts noted the Army demonstrated overlooking stakeholder perceptions when the contractor viewed the assessment as a hurdle instead of an opportunity to collaboratively develop a risk perception plan and community communication plan. Experts also noted the lack of a comprehensive communication plan, evidenced by lack of available documentation regarding a technical and communication risk assessment plan. Expert reviewers, and also the local community, questioned the Army's plans regarding building new facility and also expanding existing facility from a safety perspective, based upon historical LAIs and lack of reporting oversight. Demonstrating a lack of progressive communication or perception practices, the Army thrust the laboratory expansion concept on the local community with little opportunity for input or feedback.

6.2.2 *NBAF*

Community stakeholders' website reflects distrust regarding state and federal authorities' capability to coordinate appropriate responses to a possible FMDv

outbreak. Community stakeholders echo the GAO concern regarding possibly underestimating the potential subsequent economic impact of an FMDv release. As stated prior, GAO published the U.S. has been FMDv disease-free since 1929, and estimated economic impacts associated with potentially losing this disease-free status at \$50B or more. Kansas residents independently voiced concerns regarding potential loss of “FMDv-free” status. Expert independent reviewers specifically noted DHS and USDA habitually neglected to address these concerns within the risk assessments, in addition to noting risk assessment technical deficiencies. Requested by Congress, GAO and community stakeholders, USDA and DHS have yet to publish their estimates of potential economic impact responding directly to address this specific concern.

Agencies responsible for NBAF neglected iterative risk communication planning throughout the process to improve stakeholder engagement, evidenced by opposing messages on each organization’s sponsored website, and documented within the expert reviews. From the evidence, Kansas residents and Kansas officials remain at odds regarding the safety, responsiveness, and disease-progression prevention mitigation methods should a release of FMDv occur. Agency efforts fail to capture and address stakeholder concerns; neglect collaborative communication methods with stakeholders to capture their perceptions regarding FMDv release; and fail to include public perception management into the risk analysis and assessment. Instead, agencies paid double for identical risk assessments, with duplicative potential hazards, and duplicative technical deficiencies in the assessments. Analogous to Fort Detrick, DHS and

elected Kansas officials thrust NBAF concept and construction on the local community with little opportunity for input, feedback, reinforcing stakeholder perceptions associated with poor agency performance.

6.2.3 *DRMS*

The DRMS levee assessment suffered from a lack of collaboration, evidenced by the legislature mandating levee hazard assessments and technical sustainability; and the Municipal Water Board criticizing the assessment for neglecting to include water availability and Delta environmental ecologic sustainability. Thus two agencies described different, and opposing, agendas and processes for the levee assessment at the outset.

The DRMS assessment focused on levee breaches, neglecting and overlooking public perceptions regarding ecologic concerns and water availability concerns. The risk assessment engineers missed a potential opportunity to expand the assessment to include addressing public perceptions. Lack of communication planning evidenced by a missing constructed communication plan of levee breaches for public consumption, in appropriate language designed to seek public understanding and feedback. Instead, assessment feedback was limited to technical experts and the Municipal Water Board, although comprehensive public stake in Delta water resources remains a politicized topic throughout California.

The risk assessment engineering team demonstrated few progressive practices regarding stakeholder engagement or communication planning. The engineers missed opportunities to collectively draw all stakeholders into the conversation regarding

validity and potential inclusion of the co-equal, yet opposing, water availability and management goals. Instead, these co-equal and opposing goals of water availability and management continue to separate stakeholders who should be collaboratively working together to solve their water dilemma.

6.3 No Communication & Perception Planning: Coeur d' Alene

Ignoring evidence coupled with no stakeholder management plans resulted in a hazardous Superfund Site which will likely never achieve sufficient environmental remediation in Coeur d' Alene. Mining interests overlooked environmental and health detrimental evidence as vegetation and marine life suffered and died. Citizens developed symptoms from what we now recognize as environmental contamination exposure. Sloppy regulation practices at the time included purchasing pollution rights, which we recognize today as substantially immoral, and illegal. Coeur d' Alene serves as a clear bellwether to evaluate the present evidence balanced against obvious environmental and health concerns; ignoring the evidence serves no purposes, or stakeholders, long-term, and instead causes much harm.

Environmental perception progression associated with Coeur d' Alene serves to warn ecological scientists and risk assessors regarding moving forward in the face of detrimental evidence, and to proceed with caution, including all stakeholders, and evaluating the evidence, as well as including stakeholder perceptions. Coeur d' Alene reflects a contaminated memorial to poor perception management practices, which should be completely avoided going forward.

6.4 Future Research: Stakeholder Engagement RPM

Modern risk assessments are often limited to technical information developed by technical experts for technical experts. Modern project complexity includes multiple stakeholders and their perceptions; multiple impacts beyond those contained in the traditional risk register development; and complex communication elements across varied social and traditional media outlets. As the technology of conducting risk assessments evolves, our engineering practice should likewise expand to encompass stakeholder engagement and communication planning practices.

Risk probabilities typically are difficult to comprehend by lay community stakeholders, leading to community stakeholders' shifting the assessment focus from expert judgments to NIMBY-related concerns. Some could argue community stakeholders simply don't understand the assessments. The probabilities contained within engineering technical risk assessments demonstrated in these cases suggest community stakeholder misunderstanding, decreasing stakeholder engagement. As the engineering teams developed communication plans, engaging stakeholders in the data-gathering and feedback process loops, stakeholder engagement increased to the point of project success and acceptance. Using social science theories, expanding risk assessment practice beyond technical information to encompass comprehensive stakeholder management and risk communication practice serves public and project interest.

NEIDL and IPET demonstrate increasing risk assessment value to stakeholders by including perceptions and communication planning through each hazard identified in the risk register. Presented through the lens of stakeholder engagement and risk

communication, Fort Detrick, NBAF and DRMS connect reducing risk assessment value, ultimately leading experts to repeatedly question the risk assessment processes. Coeur d'Alene demonstrates risk engineering community consider including perceptions within mitigation plans, as Crouch's critical assessment of the remediation plan unknowingly serves this research as the data outlier.

Engineers possess deep knowledge and expertise providing computer-generated technical risk assessments for large complex projects. The conclusions presented by these cases indicate engineers possess and sufficiently utilize technical skills and tools within risk assessments. Expanding risk registers of complex projects to include stakeholder perceptions associated with each hazard, and designing communication plans to improve sharing technical risk assessment and analysis information increases project stakeholder engagement, thus increasing risk assessment decision-making value. This research connects expanding engineering risk assessment to include perception management into communication plans through risk registers using a Risk Perception Management (RPM) Plan.

Community resistance to a project signals the initiation of an RPM. The RPM provides a tool for engineers to understand the genesis of resistance using a data-driven process instead of an emotional-driven process. Taking additional project time to capture stakeholder concerns with each item in the risk register seems counterproductive. Considering NEIDL demonstrated the use of an RPM, that project demonstrated the benefits associated with the process. The RPM enables cultivating trust between an agency and its public constituents. This research shows building stakeholder confidence by connecting stakeholder perceptions into the risk

register and developing communication plans based upon those perceptions, affects project, and potentially agency, success.

6.5 Final Thoughts

This research suggests a process to increase risk assessment decision-making value within federal agencies. The developed process depends upon agency willingness to include all stakeholders across multiple agencies as necessary; to engage stakeholders iteratively; to capture stakeholder perceptions connected to each risk register hazard; to plan risk communication considering stakeholder perceptions; and thus improve the risk assessment process. The cases in this study benefit from broader, cross-disciplinary risk assessment, including all stakeholders, iterating the risks and options, extending quantification beyond probabilities, and improving risk assessment practice by considering stakeholder perceptions and risk communication through the novel concept of an RPM.

The literature provides a comprehensive discussion regarding extending risk assessment beyond numbers, into presenting risk quantifications in a manner valuable for decision-making. We suggest, along with social scientists, the presentation method affects the decision-making process and choice perceptions. Social science experts recommend including communication strategies and stakeholder perceptions into the risk assessment process, enabling valuable decision-making and comprehensive stakeholder participation. A recent published brief regarding community perceptions of perceived flood risk in New York City specifically

suggests changing communication strategies to modify public perception, thus reducing risk of loss (Botzen, Kunreuther, & Michel-Kerjan, 2014).

Risk assessment implies both the action of technical assessment, or development of a tangible deliverable, depending upon the context. As a verb, risk assessment extends into capturing and modifying the process employed to conduct an understanding of the hazards and their consequences, options available to mitigate the risks, and contingency plans if the hazards occur. A risk assessment deliverable enables decision-making. The risk engineering assessment process considered in this study informs stakeholder management, resulting in enabling stakeholder decision-making. The cases presented here suggest extending risk assessment beyond probabilities and into stakeholder perception and communication management, as elements of the risk register. Connecting perceptions and planning communication via the risk register represents a difference from project communication planning practice.

Our six cases demonstrate increasing risk assessment value associated with broadening engineering risk assessment processes beyond technical expertise. Incorporating stakeholder perceptions into risk communication planning serves to improve stakeholder engagement. We introduce the Risk Perception Management (RPM) plan as a tool to facilitate improving stakeholder engagement, and thus increase risk assessment value.

We recognize probability, uncertainty, and variability form the foundation of engineering risk assessments. Social experts indicate stakeholders struggle to perceive small probabilities. Social experts also suggest stakeholder perceptions

regarding hazards inform stakeholder understanding regarding risk uncertainty and variability, extending risk quantification into risk communication. Thus, stakeholder perceptions inform risk communication. Improving stakeholders' understanding of risks associated with complex projects adds value to the risk assessment and decision-making processes by increasing stakeholder engagement and producing more comprehensive risk assessments. Prescribing specific social and technical processes to capture stakeholder perceptions depends directly on the risk register of the project.

We suggest a process algorithm for the RPM process:

- Risk Perception Management Plan Process
 - Begin with Risk Register, Stakeholders, and social science experts
 - Capture stakeholders' perceptions regarding each risk within the register
 - All perceptions are valid and credible at this stage
 - Collaborate with social scientists
 - Stakeholder perceptions inform risk analysis communication
 - Collaboratively develop mitigation plans informed by stakeholder perceptions
 - Collaboratively design communication plans informed by stakeholder perceptions
 - Iterate the process as the risk assessments evolve
 - Update the communication plans according to stakeholder perception and engagement changes

Employing the RPM at the beginning of risk assessments broadens project risk

management to include:

- Collaborating between risk engineers and social scientists early in the process
- Including social expertise to capture stakeholder perceptions
- Collaboratively developing and delivering associated risk communications
- Iteratively updating the risk assessment, resulting stakeholder perceptions, and communications

Characteristics of successful comprehensive communication planning include collaborative conversations to gather stakeholder perceptions; comprehensive community stakeholder involvement insuring representation from all stakeholders; clear articulation regarding risks and mitigation efforts using audience-appropriate language; providing progressive iterations via public forums throughout the risk assessment process to inform stakeholders and gather their feedback throughout the process; experts providing clear connections between the risk(s) and decision(s) at-hand throughout the process, including audience-appropriate language documenting risk assessment changes and decisions associated with each iteration; and agency responses reflect each stakeholder concern. Developed collaboratively between technical and social experts, these elements reflect sharing ideas, capturing concerns, and achieving stakeholder understanding, thus improving stakeholder engagement and risk communication. Experts continually criticize engineering risk assessments which exclude stakeholder perceptions of risk probability, uncertainty, and variability. The RPM presented here serves as a tool to begin to address those criticisms.

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