DOE-FIU SCIENCE & TECHNOLOGY WORKFORCE DEVELOPMENT PROGRAM

STUDENT SUMMER INTERNSHIP TECHNICAL REPORT

June 21, 2010 to August 27, 2010

Risk Assessment in Support of DOE Nuclear Safety

Principal Investigators:

Leydi Velez (DOE Fellow)
Florida International University

James Hutton, Mentor
Safety and Security Program – EM 20

Acknowledgements:
Steve Krahn, DAS, Safety and Security Program EM-20
James O'Brien and Samuel Rosenbloom, Office of Nuclear Safety Policy, HS-21
David Kosson, CRESP/ Vanderbilt University

Florida International University Collaborator and Program Director:

Leonel Lagos, Ph.D., PMP®

Prepared for:

U.S. Department of Energy
Office of Environmental Management
Under Grant No. DE-FG01-05EW07033

ABSTRACT

In the summer of 2010, DOE Fellow Leydi Y. Velez participated in a summer internship at DOE Headquarters in Washington, DC. She worked for the Office of Safety and Security under the supervision of James Hutton. Leydi's role was to assist the Office of Environmental Management (EM) in the implementation plan for the Defense Nuclear Facility Safety Board's Recommendation 2009-1. Leydi assisted in the study of the applications of risk assessment and management tools at other government agencies and organizations. Evaluation of the results of the research study will help DOE determine what directive changes are necessary and appropiate, including the issuance of a specific policy on the use of quantitative risk assessment to allow or control its use in its nuclear safety applications at defense nuclear facilities. Concurrently, she assisted EM in the preparations for a workshop on risk assessment and decision making under uncertainty which was hosted by the Consortium for Risk Evaluation with Stakeholder Participation (CRESP), Vanderbilt University, and DOE. This report will give an overview of the tasks Leydi performed during the internship, focusing on the study of applications of risk assessment and management tools at other government agencies as well as the details of the preparations for the risk workshop.

TABLE OF CONTENTS

ABSTRACT iii
TABLE OF CONTENTS iv
LIST OF TABLES v
1. INTRODUCTION 6
2. EXECUTIVE SUMMARY 8
3. RESEARCH DESCRIPTIONS 9
3.1 Purpose 9
3.2 Method 9
4. RESULTS AND ANALYSIS 12
4.1 Literature Review 12
4.1.1 Assessing Nuclear Power Plant Risk Management Effectiveness 12
4.1.2 Risk Informed Decision Making for Nuclear Material and Waste Applications – NRC Guidance Document. 13
4.1.3 Nuclear Regulatory Commission Risk Management 15
4.1.4 Report by the Independent Review Team on Hydrogen in Piping and Ancillary Vessels Concerning the Pretreatment Facility of the Hanford Waste Treatment Plant 16
4.1.5 Applications of Risk Assessment and Risk Management Tools at Other Agencies and Organizations- Draft Report 19
4.2 Center for Strategic & International Studies: Risk Management Non-DoD US Agencies Workshop – Lessons Learned and Best Practices 20
4.3 DOE Interview with FAA 21
4.4 Workshop on Safety Decision Making Under Uncertainty 22
5. CONCLUSION 25
6. REFERENCES 26
APPENDIX 27

LIST OF TABLES

Table 1. Summary of Other Agencies..... 19

1. INTRODUCTION

Risk management has become a critical part of strategic management in both the private and public sector. DOE uses risk assessments and risk management processes to support various decisions. Such decisions may be in areas of nuclear and facility safety, project management, security, environmental management, radiation protection, and waste management. Currently, DOE manages the safety of its nuclear operations by ensuring rigorous implementation of its safety requirements, including those in 10CFR Part 830, *Nuclear Safety Management*, for identifying and analyzing hazards, and identifying engineering and administrative controls to mitigate the hazards. DOE-Standard (STD)-3009, *Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analysis*, provides a clear direction on the analyses that are required to support safety basis decisions. However, the standard does not require or expect the additional detail and technically disciplined analysis necessary for a quantitative or probabilistic risk assessment.

On August 12, 2009, the Defense Nuclear Facilities Safety Board (DNFSB) issued recommendation 2009-1, *Risk Assessment Methodologies at Defense Nuclear Facilities.* This recommendation identified "the need for adequate policies and associated standards and guidance on the use of quantitative risk assessment methodologies at DOE's defense nuclear facilities." The Secretary of Energy accepted the Board's Recommendation on November 3, 2009, and provided the Board DOE's initial implementation plan for the recommendation. On February 1, 2010, as a follow on to DOE's acceptance of the DNFSB Recommendation, the Secretary committed to the revision of DOE's Nuclear Safety Policy to address the use of quantitative risk assessments in nuclear safety.

The implementation plan for Recommendation 2009-1 includes the following items.

1) Complex-wide information notice to provide interim advice about existing policies on use of quantitative risk assessment in nuclear facility applications.
2) Charter a Risk Assessment Technical Expert Group (RWG).
3) Update the Nuclear Executive Leadership Training.
4) Develop a new course on risk assessment for staff and managers.
5) Perform a study of the use of quantitative risk assessment methodologies at DOE and other government agencies and industry.
6) Following the completion of this study, determine the appropriate department-specific guidance, standards or policy expectations that are necessary to ensure the appropriate and consistent use of quantitative risk assessment in nuclear safety analysis.

The implementation plan is currently being carried out by the Chief of Defense Nuclear Safety and the Chief of Nuclear Safety staff from the Office of Health, Safety, and Security (HSS) along with representatives from the Office of Environmental Management (EM). Leydi served as a liaison between EM and the staff from HSS during the execution of the external review study and the preparations for the workshop.

Evaluation of the results of the planned external and internal review will help DOE determine what directive changes are necessary and appropiate, including the issuance of a specific policy on the use of quanitative risk assessment to allow or control its use in its nuclear safety applications at defense nuclear facilities.

2. EXECUTIVE SUMMARY

This research work has been supported by the DOE-FIU Science & Technology Workforce Initiative, an innovative program developed by the US Department of Energy's Environmental Management (DOE-EM) and Florida International University's Applied Research Center (FIU-ARC). During the summer of 2010, a DOE Fellow intern (Ms. Leydi Velez) spent 10 weeks doing a summer internship at DOE Headquarters for the Office of Safety and Security under the supervision and guidance of James Hutton. The intern's project was initiated in June 21, 2010, and continued through August 27, 2010 with the objective of assisting the Office of Environmental Management (EM) in the implementation plan for the Defense Nuclear Facility Safety Board's Recommendation 2009-1.

Risk management has become a critical part of strategic management in both the private and public sector. DOE uses risk assessments and risk management processes to support various decisions. Such decisions may be in areas of nuclear and facility safety, project management, security, environmental management, radiation protection, and waste management. On August 12, 2009, the Defense Nuclear Facilities Safety Board (DNFSB) issued recommendation 2009-1, *Risk Assessment Methodologies at Defense Nuclear Facilities.* This recommendation identified "the need for adequate policies and associated standards and guidance on the use of quantitative risk assessment methodologies at DOE's defense nuclear facilities." The Secretary of Energy accepted the Board's Recommendation on November 3, 2009, and provided the Board DOE's initial implementation plan for the recommendation. DOE believes that a study of the risk assessment-related policies, standards, guides, and other controls used by other government organizations, as well as by industry, is useful to ensure that the Department can take full advantage of the available risk assessment tools, best practices, and lessons learned from across the spectrum of experienced practitioners.

DOE Fellow Leydi Velez served as a liaison between EM and the staff from HSS during the execution of the external review of risk assessment-related policies, standards, guides, and other controls as well as in the preparations for a Safety Decision Making under Uncertainty Workshop.

Evaluation of the results of the planned external and internal review will help DOE determine what directive changes are necessary and appropiate, including the issuance of a specific policy on the use of quanitative risk assessment to allow or control its use in its nuclear safety applications at defense nuclear facilities.

3. RESEARCH DESCRIPTIONS

3.1 Purpose

DOE believes that a study of the risk assessment-related policies, standards, guides, and other controls used by other government organizations, as well as by industry, is useful to ensure that the Department can take full advantage of the available risk assessment tools, best practices, and lessons learned from across the spectrum of experienced practitioners. For this reason, DOE decided to take the following actions:

1. Perform a study of the use of quantitative risk assessment methodologies at DOE and other government agencies and industry.
2. As part of this study, evaluate DOE's present use of risk assessment tools in nuclear safety-related decision-making and identify any opportunities for improvement.
3. Following the completion of this study, determine the appropriate Department specific guidance, standards or policy expectations that are necessary to ensure the appropriate and consistent use of quantitative risk assessment in nuclear safety analysis.

This study is being executed by the staff from the Office of Nuclear Safety, Quality Assurance, and Environment within HSS in collaboration with staff and managers from EM, Nuclear Energy, and Science, and the National Nuclear Security Administration. This core team will be supported by Federal staff and contractors from DOE sites and national laboratories.

The purpose of the study is to collect information from DOE and contract managers, as well as subject matter experts from other Federal agencies, on:

1. Applications where quantitative and/or qualitative risk assessments are utilized.
2. Types of risk assessments and risk management tools that are used in these applications.
3. Controls (e.g., procedures, quality assurance requirements) that support proper use of risk assessments and risk management tools.
4. Infrastructure (e.g., training, subject matter expert teams) in place to support proper use of risk assessments and risk management tools.

3.2 Method

A data collection team scheduled meetings with DOE managers from the sites, and also other government agencies, to discuss with them the details of their applications of risk assessments. Prior to the meeting, the data collection team provided the interviewee with a set of questions to facilitate the discussion.

The organizations selected for interviews were:

- National Aeronautics and Space Administration (NASA)

- U.S Nuclear Regulatory Commission (NRC)
- Nuclear Energy Institute (NEI)
- Food and Drug Administration (FDA)
- Federal Aviation Administration (FAA)

Additional organizations may be interviewed if time permits.

The internal survey included DOE sites and laboratories such as:

- Idaho National Laboratory
- Savannah River Site
- Pacific Northwest National Laboratory (PNNL)
- Office of Science at PNNL
- Hanford Site
- Pantex Plant
- Los Alamos National Laboratory
- Y-12 National Security Complex

Two different reports are being developed: one for the study of current DOE applications of risk assessments and another for applications of risk assessments at other government agencies and in related industries.

Leydi had the opportunity to participate in the interview with FAA as well as provide feedback on the initial draft of the report entitled, *Applications of Risk Assessment and Risk Management Tools at Other Agencies and Organizations.* This report includes results of the interviews and observations and potential lessons learned.

In addition to the one-on-one interviews with DOE and other agencies, it was suggested that DOE held a workshop with the same purpose of understanding the state-of-the-science for the use of probabilistic risk assessment techniques. To do this, DOE partnered with the Consortium for Risk Evaluation with Stakeholder Participation (CRESP***)***, which is a consortium of universities working to advance cost-effective, risk-informed cleanup of the nation's nuclear weapons production facility sites and cost effective, risk-informed management of potential future nuclear sites and wastes.

The objective of this workshop was to:

1. Exchange information on the current approaches to safety assessment and decision making across a range of federal agencies, industries, and researchers.
2. Identify best practices
3. Identify key knowledge and methodological gaps and research needs.

Representatives from DOE, NRC, Department of Defense (DOD), NASA, FAA, Department of Homeland Security (DHS), national laboratories, academia, and nuclear, aerospace, chemical industries attended the two day workshop. Leydi contributed to the preparation of this workshop by helping create the agenda, obtaining contact information of the participants and attendees and processing the concurrence package for DOE approval prior to sending out

the formal invitations memos. Following the completion of her internship, Leydi was invited by CRESP to assist the team during the workshop.

4. RESULTS AND ANALYSIS

During the course of the summer internship, Leydi reviewed several papers on the topic of risk management in order to gain a better understanding and provide feedback and comments to the implementation plan core team. This included information on current guidelines, policies, and lessons learned from other agencies. The following is a summary of some of the literature reviewed by Leydi, her comments on the initial draft of the external review of risk assessment applications at other agencies and organizations, as well as details of her participation in a risk management workshop hosted by the U.S Defense and National Security Group at the Center for Strategic and International Studies (CSIS). This section will also include details on two of DOE's interviews with FAA in which Leydi participated. In addition, Leydi had the opportunity to provide input into the agenda for the workshop on Risk Assessment and Safety Decision Making under Uncertainty hosted by DOE and CRESP on September 21-22, 2010. She was invited to the workshop and assisted the staff during both days.

4.1 Literature Review

4.1.1 Assessing Nuclear Power Plant Risk Management Effectiveness

Technical Report Summary

Application of an effective risk-management process consists of the following four elements:

1. Identifying risks
2. Quantifying and prioritizing risk contributors
3. Responding to indicators of risks or adverse trends
4. Maintaining a risk-management culture

In the application of risk management to proposed plant changes (including design, procedural, programmatic, and organizational changes), quantifying and prioritizing risks consists of much more than using the Probabilistic Risk Assessment (PRA) to predict the future risk of the proposed change. It also includes the monitoring of risk rates as plant configurations are planned and implemented, monitoring leading indicators that foreshadow changes in risk, and calculating risk after implementation to document the actual risk levels that occurred as a result of the change.

Maintaining a risk-management culture ensures that the process is effective and that it evolves to address emerging issues and incorporates lessons from plant and industry operating experience.

The approach to achieve this objective is to embed appropriate risk analysis tools (from qualitative methods using simple business principles to quantitative methods such as construction of decision trees and calculation of some standard metric such as expected monetary value for each of the possible alternatives) and management controls into the various plant processes. This ensures that appropriate analysis methods are applied, based on the economic significance of the decision, and that decisions are made at an appropriate level

within the organization. This approach also ensures that decisions are made in a cost-effective manner with input and concurrence of the various stakeholders.
Because of these distributed responsibilities, an important element of ensuring effective risk management is the interface between the various organizations responsible for decisions, with potential risk implications. Thus, an important element of risk management is to ensure that the various processes permit efficient dissemination of information and that the interfaces between organizations are effective at communicating this information and working in a collaborative manner to reach appropriate decisions.

4.1.2 Risk Informed Decision Making for Nuclear Material and Waste Applications – NRC Guidance Document.

Summary and Observations

This document contains guidance on how to make appropriate risk-informed regulatory decisions for nuclear material and waste applications. Regulatory situations that would most benefit from the methods in this guidance document are those for which an understanding of risk and other factors is needed to support a good decision, but for which such information may not be readily available.

Overall, this document provides a step-by-step procedure on how to make risk informed regulatory decisions by providing an overview of risk informed decision making concepts, and by providing a risk-informed decision making process. This document is intended to familiarize staff from the Nuclear Material Safety and Safeguard (NMSS) and the Office of Federal and State Materials and Environmental Management Programs (FSME) staff with the risk informed process and when it should be applied. The methods presented are intended to be generic (widely applicable across diverse activities) and considers all relevant attributes and not just risk. This guidance identifies the type of risk to calculate the criteria to consider, and the methods of integrating risk.

The risk informed decision process as explained in this document is as follows:

1. **Define the regulatory issue (or problem) and preliminary alternative actions.**
2. **Decide whether to risk-inform** (Provides a list of screening considerations to determine the benefits and the feasibility of the risk assessment).
3. **Perform risk assessments as needed** (Surveys the range of methodologies available and provides guidelines how to select an evaluation approach in a particular problem area).
4. **Apply Risk Informed Decision Making (RIDM) method**. (Provides specific decision making algorithms, as well as value impact analysis examples).

Three tools are explained in this document: Probabilistic Risk Analysis (PRA), Integrated Safety Analysis (ISA), and Performance Assessment (PA). For each of these tools, a description is provided along with examples of applications in the nuclear material and waste applications.

In addition, this document includes a section on risk guidelines, such as the Three-Tier Approach (Tier I-Qualitative, Tier II-Quantitative, and Tier II-Subsidiary Objectives) used in the RIDM algorithms and which represent an accident risk reference level regarded as a negligible additional risk, compared to the normal risks faced by workers or the public. Finally, this document includes a section on risk communication which provides a guideline for documenting and communicating risk decisions to various stakeholders.

This document is a supplement to the existing NRC guidance on the use of risk information, and in addition, there are numerous references to different NRC guidelines which support various aspects of the decision making process. *"The majority of material licensing applications are not expected to require sophisticated risk analyses.* ***It should be noted, however, that, compared to operating power reactors, the application of risk assessment to the very diverse set of NMSS/FSME-regulated activities and facilities is in a relatively early stage."*** **[9].**

Observations

This guidance provides a well documented process for conducting risk informed decisions. In this case, the examples are focused specifically on regulatory decisions such as exemptions or changes to regulatory requirements, and imposition of new regulatory requirements. However, an effort was made to define it in such a way that it could be applied to other types of scenarios. DOE can attempt to copy this concept by analyzing the result of the interval survey of risk assessments and identifying those common areas in which RIDM are used in order to provide a similar decision making process. The lessons learned from the internal survey and the external review should help identify the specific topics that should be included in the guideline in addition to the level of detail that should be covered. Prior to publishing the guideline, DOE should conduct several case studies to determine the applicability of the decision making process and to identify further improvements. It should be kept in mind that this document is intended to be a "living document" and could be updated as needed.

Depending on the complexity of the decisions and the variety of the methods that could be applied, DOE could consider providing template forms which facilitate the documentation of the process by allowing the users to follow a standard method. An example can be seen in the approach used by National Nuclear Security Administration Nevada Operations Office (NNSA/NV) to assure that programs and projects incorporate appropriate, efficient, cost-effective measures to mitigate the impact of program-and/or project-related risks. NNSA/NV defined a very simple risk management plan which includes a risk assessment form, risk screening guidelines, and a risk analysis process [8].

The following are points brought up in the NRC Guidance Document [9]:

- *"The choice of a particular method will depend on the reason for conducting the analysis, the results needed, the information available, the complexity of the process, the availability of experience personnel, and the perceived risk of the process."*

- *"Risk analyses should be performed on a best-estimate, realistic basis. Staff should avoid both conservatism or optimism should be in arriving at the final results. Ideally, all parameters and models that make up the risk analyses would be characterized by uncertainty distributions that would encompass the range of physically realizable situations. These uncertainties would be continued throughout the analysis and would be included in the end results."*

- *"It is important that staff fully understand uncertainties and sensitivities before a decision is reached."*

References of interest

1. International Atomic Energy Agency (IAEA) report contains a discussion of evaluation needs for applying a risk-informed approach to the materials and waste arenas. Particular attention is given to the products of an analysis as they will be vital to the end-uses to which they will be applied. The IAEA report is a collaborative effort of several countries with an interest in risk-informed approaches to nuclear technology. It is a state-of-the-art exposition and represents convergence of thought on methodological approaches. The present guidance relies heavily on the information contained in the IAEA report.

2. Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," encourages the increased use of PRAs to improve safety decision making and regulatory efficiency for reactors.

3. NUREG/CR-2300, "PRA Procedures Guide - A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants" and NUREG/CR-2815, "Probabilistic Safety Analysis Procedures Guide" .

4. Staff has endorsed the PRA standards in RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities."

5. The understanding and modeling of human behavior related to accident evolution is important in PRA. This area has been the focus of extensive research, and NUREG/CR-1278, "Handbook of Human Reliability Analysis" provides examples of the results. Software models for the evaluation of human performance are also available.

4.1.3 Nuclear Regulatory Commission Risk Management

Leydi also looked into the NRC website to find out if they have any plans to update their standards on risk management for their nunclear materials sector. She looked into their current Staff Requirements Memorandum (RSMs) but did not find anything related to the subject of risk management. Based on the information available through the NRC webiste the

following observations were made:

- In the spent fuel subarena, the NRC staff is limited in its ability to risk-inform the agency's regulatory activities because it is not cost-benefitial to perform a risk-assessment of each of the numerous storage or transportation designs. "Staff may apply RA to specific activities on a case by case basis, provided that the screening criteria (provided in the *Risk Informed Decision Making for Nuclear Material and Waste Applications Guidance*) are meet."
- At this time, the staff of NRC has not established risk-informed and performance-based rule making nor oversight activities for the low-level waste and decon sub-arenas.

In summary, the only guidance available for the nuclear material division is the *Risk Informed Decision Making for Nuclear Material and Waste Applications Guidance*.

One of NRC's partners in their risk management efforts is the Electric Power Research Institute (EPRI). EPRI has a Risk and Safety Management Program where they support industry efforts to ensure risk-informed approaches can be used making operational, maintenance, and regulatory decisions impacting nuclear power plants. Some of the projects EPRI is working on are research to facilitate the development of a risk informed framework, development of risk assessment tools, and risk and safety software codes, among others. Currently, NRC and EPRI will be hosting a training session on fire probabilistic risk assessment which will take place on August 27, 2010. EPRI has several reports on their website (http:www.epri.com) and some of them are free. However, their research is focused on the nuclear sector and DOE does not manage this type of facility.

4.1.4 Report by the Independent Review Team on Hydrogen in Piping and Ancillary Vessels Concerning the Pretreatment Facility of the Hanford Waste Treatment Plant

Summary and Recommendations from Review Team

An independent review team (IRT) was assembled by Bechtel National, Inc. (BNI) to review a new design approach for hydrogen in the piping and ancillary vessels (HPAV) of the pretreatment facility (PTF) at the Hanford Waste Treatment and Immobilization Plant (WTP). In 2002, the NRC issued notice 2002-15 "Hydrogen Combustion Events in Foreign BWR Piping." In accord with their procedures, BNI and DOE Office of River Protection (ORP) reviewed this nuclear operating experience and became concerned with potential hydrogen accumulations in piping and ancillary vessels of the PTF during normal operations, anticipated operational occurrences and upset conditions. Accordingly, a project was undertaken to improve the design of the PTF to manage the accumulation of hydrogen in piping under such conditions. The design of the PTF to deal with hydrogen in the years leading up to 2008 resulted in a level of complexity that concerned ORP and BNI from operational and safety perspectives. Because of a growing concern over the complexity of the design, ORP chartered two task forces early in 2009 to determine whether alternate design approaches for dealing with hydrogen, particularly hydrogen that might accumulate in piping systems, would simplify the facility, thus providing higher assurance of safe and reliable operations while protecting the long term availability of the facility. As a result of these task forces, BNI adopted a new design strategy to prevent damage from explosions in HPAV

piping and components through a combination of active and passive control measures and safety features.

Design decisions on which passive or active safety systems are to be chosen for a particular route will be made on a route-by-route basis. The new approach includes a quantitative risk analysis (QRA) model that was developed to determine the potential combustion loads for each pipe route. The QRA model will be capable as well of informing decisions about alternative design and operational strategies to prevent and mitigate hydrogen events in piping systems, thus facilitating design optimization.

On April 2010, during a periodic report to Congress, DNFSB suggested that DOE undertake a comprehensive, independent, expert-based review of the safety design strategy for control of hydrogen in pipes. The review is intended to provide added assurance that the criteria and methodology provide a technically defensible and conservative approach to ensure the safety and reliability of the WTP design. The IRT concluded that the new design approach for HPAV piping and components is acceptable provided BNI improves the models, assumptions and methodology involved in the approach to close the IRT's Findings.

QRA Method

The method used for QRA includes:

1. Fault trees
2. Event trees
3. Monte Carlo uncertainty analysis
4. Post processing results

Overall recommendations from IRT for long-term improvements in risk-informed approach to design

1. The QRA should not be used as the sole justification for any design alternative.

2. A comprehensive description of the methodology should be documented and should state the major assumptions and their bases, summarize the calculation methods, identify key supporting documents and summarize the results.

3. Justification for the selection of a QRA methodology, its parameters, distributions, stimulants, and scenarios should be fully documented.

4. If data such as initiating events and event sequences are extracted from previous studies, they need to be reviewed to confirm applicability to the current model and to account for the different purposes of the QRA and those of the previous studies.

5. Justification for screening out any events is an important element of the QRA documentation and needs to be added. A set of quantitative and qualitative screening criteria should be developed for this purpose. The criteria need to be selected to ensure that the frequency of any screened out event of a given severity potential is an insignificant fraction of the total frequency of unscreened events at the severity level.

6. The duration of an event needs to be considered as part of the severity potential and thus included as a parameter for the screening criteria.

7. ASME/ANS PRA Standard- has been endorsed by the US NRC in Regulatory Guide 1.200. According to this standard, events less likely than 10^{-8} per plant year may be screened out as beyond the de minimus level, and events less than 10^{-6} per plant year may be screened out as long as the capabilities of the containment are not compromised.

8. The technical basis for the number of duration bins of events modeled in the QRA, the selection of the distribution type, and the parameters of the associated uncertainty distributions needs to be strengthened.

9. The final production version of the QRA needs to avoid the use of point estimates for uncertain parameters unless it can be shown that such approximation do not have a significant impact on the results.

10. Each source of uncertainty should be evaluated for its known or potential impact on the QRA results. Criteria should then be developed and applied to justify the uncertainty distributions that are applied.

11. Incorporate the applicable technical requirements from the ASME/ANS PRA standard into the quality program elements of the QRA.

12. Adopt the expert elicitation process that is used in the nuclear power industry pursuant to Section 1-4.3 of the ASME/ANS PRA Standard. This approach would apply to areas in the QRA where there is significant reliance on expert opinion and engineering judgment that is not directly supported by available data. For example, to review inputs to the QRA evaluation as well as the output to ensure consistency of the approach.

Reference of Interest

Stan Kaplan and B. John Garrick, "On a Quantitative Definition of Risk", *Risk Analysis*, Volume 1, Number 1, Page 1, January 1981, Defined the "essential elements of a quantitative risk analysis:"

1. A systematic enumeration of event sequences comprised of initiating events, plant and system response events, human actions and errors, and clearly defined end states.
2. A quantification of the frequency of each event sequence in terms of the initiating event frequencies, basic event probabilities, and uncertainties in the frequency estimates.
3. A quantification of the level of consequences or damage from each event sequence including the selection of appropriate risk metrics and a quantification of the uncertainty and variability in the level of damage

4.1.5 Applications of Risk Assessment and Risk Management Tools at Other Agencies and Organizations- Draft Report

The following is a brief summary table of key observations for each of the organizations interviewed by the staff from HSS.

Table 1. Summary of Other Agencies

	Applications	Tools	Controls	Infrastructure	Benefits
NASA	Public/Worker Safety; Mission Risk	Software adapted & developed	Requirements Documents	HQ Develops; Centers Implement	Balancing safety with mission objectives
NRC	Public Health & Safety; Informing Decisions	Specific software for all phases of evaluation	Regulatory Guides & Industry Standards	Various Implementation Offices + Research Office	Decision support; cost/benefit of new requirements
NEI	Operational Safety; Environment and Public Risk	Utilities have own tools	NRC-driven	Utility members; International participation; EPRI support	Can be useful where technology supports decisions
FDA	Food Safety Inspections	Informal techniques	International Standards and Guides; Large studies have peer review	Inspectors given risk training through institute courses	Inspection prioritization; resource management

Comments Provided to Authors

With regards to the purpose of the study, the results show essential information which gives the reader a good understanding of the risk assessment activities of the external organizations. The information is presented in a coherent manner, and the summary and observations provide DOE with good points to consider when making the decision of determining whether the use and control of risk assessment could be enhanced. The internal survey should be a complement to this report, in a sense that it should provide details on how DOE is currently applying QRA and how these methods are similar to the external agencies studied in this report. This report also cites a good number of sources which should be useful in the case that DOE decides to enhance its controls and infrastructure for risk decision making.

One thing I noticed is that the benefits section does not provide enough detail on the benefit of using qualitative risk assessments relative to its costs. Instead, it provides general areas in which the agencies have benefited from the use of QRA.

If additional agencies will be studied, it will be beneficial to use those that mostly resemble the DOE nuclear facility range. If possible, a follow-up of the potential lessons learned should be performed.

In summary, the report informs DOE that:

- There are agencies with well established controls and infrastructures which have proven beneficial to their specific area of application, and could be a good model for DOE to follow.
- Some areas such as non-reactor facilities and managing daily work do not have such well-established controls and infrastructures.
- This report could serve as a baseline to compare how DOE is currently applying QRA and how it could be improved by providing similar infrastructures.

4.2 Center for Strategic & International Studies: Risk Management Non-DoD US Agencies Workshop – Lessons Learned and Best Practices

Leydi had the opportunity to attend a risk management workshop which was hosted by the U.S Defense and National Security Group at the Center for Strategic & International Studies (CSIS). The purpose of the workshop was to present a briefing on some of the best practices and lessons learned from a literature review of risk management approaches at various agencies. This was part of an ongoing support of efforts by the Office of the Under Secretary of Defense for Policy to develop an enterprise-wide risk management framework. Representatives from a range of agencies such as Department of Defense (DOD), Department of Homeland Security (DHS), National Intelligence Council (NIC), U.S. Securities and Exchange Commission, DOE, Nuclear Regulatory Commission (NRC), NASA, U.S Coast Guard, Dept. of State, and Massachusetts Institute of Technology (MIT) participated in the workshop and provided additional insights and comments.

Some of the items that were discussed during the workshop included:

- The topic of “non-risk” factors and whether or not it should be included in the overall risk assessment. “Non-risk” factors are things like technical feasibility, government mandates, policies, and politics.
- Risk can be strategic or operational. Strategic are higher level and should answer the question, “Are we doing the right job?” Operational level answers the question, “Are we doing the job right?”
- DoD categorized risk as tactical (on ground) or operational (strategic). The U.S Coast Guard representative pointed out that strategic level can feed into the operational into the tactical.
- It is important to consider inter and intra dependencies affected by levels of risk.
- Discussed latent risk management vs. active risk management.
- Whether or not it is necessary and possible to set a common definition of risk within and among different organizations. One point of view was that currently there is a discrepancy in how risk is defined and how is interpreted by different individuals.

This can affect the consistency in which risk assessments are carried out. However, another point of view was that it would be impractical, if not impossible, to define one definition for risk given the fact that the applications are very broad and diverse even within an agency such as DOE, who currently applies risk assessment in a broad range of offices. Thus, a definition of risk based on context should be considered. This brought about the topic of a setting a risk lexicon, which should help establish a common language within the organization.

- Pros and cons of the size of the scope of risk: dependent on the type of risk, the complexity of the decision.
- Elicitation and characterization: DHS developed a methodology for elicitation which includes obtaining expert advice. The goal should be to establish a repeatable and transparent elicitation and characterization. NASA introduced a structure with emphasis on scenario-based risk characterization. They also emphasized the importance of defining success prior to commencing a risk assessment, in addition to a clear understanding of the purpose or "goal" of the risk assessment.
- The risk management cycle should be well defined
- DHS made a clear distinction between risk-informed as opposed to risk-based decision making. They emphasized the importance of making it clear to the decision makers that risk analysis is not meant to provide a decision but provide information to enable a decision.
- Discussion turned to how to embed risk management into the organizational culture. How to get people to assimilate the culture, how to get people to speak the same language? Everyone had a different perspective; some think training is not enough and top level commitment and involvement is the key to motivate and guide the people in the organization. It is an ongoing effort.
- NASA brought up the point of the importance of continuous risk management and management of the decision made.

4.3 DOE Interview with FAA

As part of the external review, HSS scheduled two meetings with the FAA. The first meeting was in the Air Traffic Safety Oversight office with Mr. Darryel Adams. Mr. Adams talked from a policy perspective on performing safety risk management. He explained their Safety Management System (SMS), which is essentially a quality management approach to controlling risk and is currently being implemented throughout the agency. Mr. Adams pointed out that their primary focus is quality assurance and that risk assessment is a low portion of it. They apply risk decision making during their audits to the air traffic operators. Only those issues that are identified as "high risk" are selected. Generally, they do very broad monitoring. Part of their responsibility is to ensure that the ATO are following the policies and standards.

The second meeting was at the Air Traffic Operations (ATO) office with two of their safety risk managers (Mr. Chris Pokorski and Mr. Mike Falterisek). They explained that safety risk management (SRM) is one pillar of their SMS. ATO implemented the SMS over the course

of 5 years. The SRM includes the processes and practices used to assess changes to the NAS for safety risk, the documentation of the risks associated with those changes, and the continuous monitoring of effectiveness of any controls used to reduce risk to acceptable levels. The SRM reference guide includes a defined SRM process, hazard analysis worksheet with definitions, severity definitions, likelihood definitions, and a risk matrix. Some of the tools they use for PRA are fault tree, events trees and a Botie (a modified version of the fault tree horizontally).

4.4 Workshop on Safety Decision Making Under Uncertainty

The workshop agenda and the logistics of the workshop were prepared by Dr. David Kosson (Vanderbilt University) with the assistance of Leydi. EM-20 DAS, Dr. Steve Krahn asked Dr. Kosson and Leydi to work together to prepare the logistics of the workshop which included names and contact information of prospective presenters, panel members, and attendees. In addition, he asked Leydi to identify some of the key topics that could be considered for discussion. Some of the topics identified by Leydi included:

Risk Management across US Government Agencies

1. What guidance or standards does your organization use for risk assessments?
2. What do you believe are the benefits and limitations (if any) of defining risk management standards?
3. What are some of the challenges that your organization has encountered while implementing a risk management strategy?
4. What do you consider to be a key factor(s) to successfully develop a risk assessment guide or standard in an organization such as DOE?
5. What criteria does your organization use to justify the use of QRA?
6. How does your organization measure/evaluate the effectiveness of a risk assessment?
7. What areas in your agencies have benefited the most from using risk assessments?
8. How has risk management improved your Agencies' efforts in reaching its goals?

Basic Principles for Identifying and Assessing Risk

1. Best practices in risk elicitation and characterization.
2. How to select a QRA tool that best fits the purpose of the assessment?
3. What are some of the common misconceptions about risk assessment tools?
4. What are the essential elements in quantitative risk assessments?
5. Best practices for establishing a risk assessment quality standard.

Treatment of Uncertainties and Assumptions in Nuclear Safety

1. Common understanding of the authorities and responsibilities for accepting risk and how it differs for nuclear safety.
2. Who should be responsible for decisions to allocate risk?
3. How can risk management incorporate uncertainty?
4. How can risk management account for dynamic threats?
5. How to balance conservatism and optimism when dealing with uncertainty parameters?
6. How to determine the appropriate criteria for deciding when to accept, transfer, or mitigate risk?
7. What are the most common sources of uncertainties and assumptions in nuclear safety?
8. Best practices for validating and evaluating a QRA model.

Risk Management: An Organizational Culture

1. How to embed risk management into organizational culture?
2. How to link organization overall strategy to risk assessment processes?
3. Best practices in risk communication within and outside organization.
4. Best practices in defining a risk lexicon within an organization.

Due to time constraints the list of topics was reduced and needed to be reorganized based on the session titles. The workshop was a two day event (September 21-22), and was held at the Marriot Hotel and Conference Center in Bethesda, MD. The workshop agenda is included in the Appendix. Leydi had the opportunity to travel to Maryland and assist the staff from CRESP during the workshop.

The following is a summary of some of the key points brought up during the workshop which can help DOE establish its roadmap towards well established organizational framework and guidance:

1. PRA is an additional tool for safety management (SM), not a substitute for other tools.
2. A screening process is needed to identify when PRA should be used.
3. Human factors are an important component of PRA and needs to consider latent and external factors.
4. Development and evaluation of scenarios provides important insights into opportunities for focusing safety improvements.

5. Communication and education is essential and an ongoing need and challenge.
6. Independent peer review is a critical part of PRA as well as other SM.
7. It is important to understand the context in which decisions are made.
8. Risk and safety analysis should be integrated.
9. Several agencies have many years of experience in this field; DOE should attempt to learn from them and partner with them during this process by sharing information and soliciting expert advice.
10. Terminology is important. Defining a risk lexicon can be the first step to elaborating a risk assessment framework.
11. Decide where risk analysis fits into the organization framework and if it does, what type of framework or guidance is required.
12. Stakeholders should be involved early and often during the risk assessment.
13. Not all cases will require extensive quantitative risk assessments; in some cases, an initial qualitative assessment can help you identify the areas which can merit a more complex deterministic study. Semi-quantitative/qualitative studies have become popular in risk assessments.

Several different points of views brought up during this workshop pointed to the fact that it has taken agencies such as NRC, NASA, DOD, and DHS many years to establish their risk management framework. Although the applications in which risk assessments are used vary greatly across these agencies and even within an organization like DOE, a good foundation will ensure that the assessments support the overall goal and mission of the organization through a transparent, well defined, and managed process.

5. CONCLUSION

Maintaining a risk-management culture ensures that the process is effective and that it evolves to address emerging issues and incorporates lessons from plant and industry operating experience. An important element of risk management is to ensure that the various processes permit efficient dissemination of information and that the interfaces between organizations are effective at communicating this information and working in a collaborative manner to reach appropriate decisions.

The external organizations that were interviewed viewed risk assessment as an integral part of their safety management programs. DOE can learn from NASA with regard to the establishment of a more formal program in risk assessment/management, if it deems that this approach would be useful to DOE. From NRC, it is readily evident that while an established and formal infrastructure exists for using probabilistic risk assessment in the operating reactor arenas, the same infrastructure does not exist in the non-reactor arenas. The non-reactor part of NRC (NMSS) has a less-established approach to use of risk approaches. NMSS has a range of facilities that more closely resemble the DOE nuclear facility range and there are some similarities in the approach to use of risk assessment and management (e.g., ISAs). DOE may want to strengthen its interactions with NRC in this area to share lessons learned and to gain an enhanced understanding of the challenges and pitfalls of introducing risk assessment in decision making in the non-reactors areas. From NEI, as a facilitator for the entire commercial nuclear industry in the U.S., DOE headquarters may want to gain a fuller appreciation of how it can support DOE field activities with risk assessment approaches. From FDA, DOE may want to explore how FDA approaches the use of informal and qualitative risk assessment in its inspection programs.

If deemed necessary, prior to publishing a formal guideline, DOE should consider conducing several case studies to determine the applicability of the decision making process and to identify further improvements. It should be kept in mind that if a formal guideline or standard is developed, it is intended to be a “living document” and should be updated as needed.

6. REFERENCES

[1] Assessing Nuclear Power Plant Risk Management Effectiveness, EPRI, Palo Alto, CA: 2004. 1008242

[2] Bechtel National Inc, Independent Review Team on: *Hydrogen in Piping and Ancillary Vessels Concerning the Pretreatment Facility of the Hanford Waste Treatment Plant,* July 12, 2010.

[3] CRESP, Consortium for Risk Evaluation with Stakeholder Participation. http://www.cresp.org/

[4] Defense Nuclear Facilities Safety Board, Recommendation 2009-1, *Risk Assessment Methodologies at Defense Nuclear Facilities,* Federal Register Notice, vol. 74, No. 154, August 12, 2009.

[5] U. S. Department of Energy, Nuclear Safety, Quality Assurance and Environment Information Notice, *Risk Assessment in Support of DOE Nuclear Safety,* June 2010.

[6] U. S. Department of Energy, Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2009-1, *Risk Assessment Methodologies at Defense Nuclear Facilities,* September 2009.

[7] U.S. Department of Energy, *Applications of Risk Assessment and Risk Management Tools At Other Agencies and Organizations*. Draft Report, prepared for DOE/HS-21, July 2, 2010.

[8] U.S Department of Energy, National Nuclear Security Administration Nevada Operations Office of Environmental Management, "Risk Management Plan", NNSA/NV-781.

[9] U.S. Nuclear Regulatory Commission, *Risk-Informed Decision-making for Nuclear Material and Waste Applications,* February 2008.

[10] U.S. Nuclear Regulatory Commission, Nuclear Materials. http://www.nrc.gov/materials.html

[11] U.S Nuclear Regulatory Commission, Risk Assessment in Regulation. http://www.nrc.gov/about-nrc/regulatory/risk-informed.html

APPENDIX

WORKSHOP AGENDA

Tuesday, September 21

7:30 a.m.-8:00 a.m. **Registration**

8:00 a.m.-9:50 a.m. **Session 1: Workshop Objectives and Challenges.**

- **Workshop introduction**
  Prof. D. Kosson, Vanderbilt University and CRESP (15 min).
- **DOE history and Needs Overview**
  Mr. G. Podonsky, Chief Health, Safety and Security Officer, DOE (15 min)
- **Defense Nuclear Facilities Safety Board Perspectives**
  Dr. L. Brown, Member, DNFSB (20 min)
- **NRC Policy and Perspectives**
  Dr. G. Apostolakis, Commissioner, NRC (30 min)
- **Making Better Decisions with Probabilistic Risk Assessment**
  Dr. B.J. Garrick, Chair, Nuclear Waste Technical Review Board (30 min)

9:50 a.m. – 10:15 a.m. **Break**

10:15 a.m.-11:00 a.m. **Session 2: DOE Activities & Challenges**
(Perspectives from EM, HSS, NNSA, 10 min each)

- Mr. D. Chung, Principal Deputy Assistant Secretary, Office of Environmental Management
- Mr. J. McConnell, Assistant Deputy Administrator for Nuclear Safety, National Nuclear Security Administration
- Mr. J. O'Brien, Director, Office of Nuclear Safety Policy and Assistance

11:00 a.m.-11:30 a.m. **One Perspective from a Chemical Industry**
S. Urbanik, Sr. Consultant, Process Safety & Fire Protection Engineering E. I. DuPont de Nemours & Company, Inc

11:30 p.m. - 12:30 p.m. **Lunch**

12:30 a.m.-2:15 p.m. **Session 3: Examples of Current Uses of Risk Assessments in Safety Decisions** (20 min. presentations + panel discussion)

- *Lessons Learned from Use of Risk Assessment Methods in the Program for Chemical Weapons Demilitarization*
  Mr. M. Evans, Sr. Vice President, URS
- *Use of PRA to support the Destruction of Abandoned Chemical Weapons*
  Dr. D. Johnson, Vice President for Probabilistic Risk Analysis and Management, ABS Consulting.
- *Risk Analysis for Truck Transportation of High Consequence Cargo*
  Dr. R. Waters, Distinguished Member of the Technical Staff, Sandia National Laboratory
- *Using Risk Analysis to Inform Strategic and Resource Allocation Decision Making in the Department of Homeland Security*
  Dr. S. Bennett, Assist. Director for Risk Analytics, Office of Risk Management and Analysis, Department of Homeland Security

Tuesday, September 21

2:15 p.m.-2:45 p.m. **Break**

2:45 p.m.-4:30 p.m. **Session 4: Examples of Current Uses of Risk Assessments in Safety Decisions** (20 min. presentations + panel discussion)

- *Safety Risk Management in Air Traffic Operations*.
  Mr. M. Falteisek, Safety Risk Manager, Office of Runway Safety, Federal Aviation Administration
- *Use of QRA as Part of HPAV Design Assessment*
  Dr. R. Bari, Senior Physicist, Brookhaven National Laboratory
- *Probability and Provability in Regulation of Food Additives and Contaminants*
  Dr. Clarke Carrington, Pharmacologist, Food and Drug Administration
- *Communicating Risk, Benefit, and Uncertainty for Biologics: A Case Study*
  Dr. M. Walderhaug, Assoc. Director for Risk Assessment, Office of Biostatistics & Epidemiology, Food and Drug Administration
- *Discussion*

4:30 p.m. **Wrap up for Day 1 and Adjourn**

Wednesday, September 22

8:00 a.m. -10:00 a.m. **Session 5: Risk, Uncertainty and Decision Making - Concepts and Methods** (20 min. presentations + panel discussion)

- *Uncertainty sources, types and quantification models for risk studies*
  Prof. B. Ayyub, Director, Center for Technology and Systems Management, Univ. of Maryland
- *Quantification of Margins and Uncertainty for Risk-Informed Decision Analysis*
  Dr. K. Alvin, Sandia National Laboratory
- *Decision-Making Under Uncertainty: Quantitative Methods*
  Prof. Sankaran Mahadevan, Vanderbilt Univ. & CRESP
- *Consideration of Human factors in Risk Assessment and Management*
  Mr. B. Hallbert, Director, Nuclear Safety and Regulatory Research, Idaho National Laboratory
- *Alternative Methods for Incorporating PRA Concepts Into the Safety Decision-Making Process*
  Prof. M. Abkowitz, Vanderbilt Univ., CRESP, and Member, Nuclear Waste Technical Review Board
- *Panel discussion*

Wednesday, September 22

10:00 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 12:15 p.m. **Session 6: Approaches to Safety Decision Making under Uncertainty – Policies and Practices** (20 min. presentations + panel discussion)

- *An Introduction to Current Practices at DOE*
  Dr. J. O'Brien, Director, Office of Nuclear Safety Policy and Assistance
- *Implementation of PRA Policy at NRC*
  Dr. M. Cunningham, Director of the Division of Risk Assessment, Nuclear Regulatory Commission
- *Risk Assessment and Risk Management Practices in the Nuclear Energy Industry*

Mr. B. Bradley, Director, Risk Assessment, Nuclear Energy Institute
- *Discussion*

12:15 p.m. - 1:15 p.m. **Lunch**

1:15 p.m. – 2:30 p.m. **Session 7: Approaches to Safety Decision Making under Uncertainty – Policies and Practices** (20 min. presentations + panel discussion)

- *DHS Policies and Processes to Guide Integrated Risk Management*
  Mr. S. Breor, Deputy Director, Office of Risk Management and Analysis, and Dr. R. Kolasky, Assist. Director for Risk Governance and Support, Department of Homeland Security
- *NASA's New Risk Management Approach*
  Dr. H. Dezfuli, NASA Technical Fellow (System Safety), NASA
- *Predicting Risk Through Modeling of Leaker Plumes*
  Mr. A. Cushen, P.E., Chief, Occupational Health and Safety, US Army Chemical Materials Agency
- *Title TBD*
  Mr. D. Adams, Manager, Safety Management Branch, Air Traffic Safety Oversight Service, Federal Aviation Administration
- Discussion

2:30 p.m.-2:50 p.m. **Break**

2:50 p.m. -3:30 p.m. **Session 8: Summary and Future Needs (D. Kosson/S. Mahadevan to lead discussion)**

- Best practices
- Knowledge and methodology gaps
- Research and education needs

3:30 p.m. **Conclusions and Adjourn**