Risk-Informed Decisionmaking for Nuclear Material and Waste Applications

Revision 1

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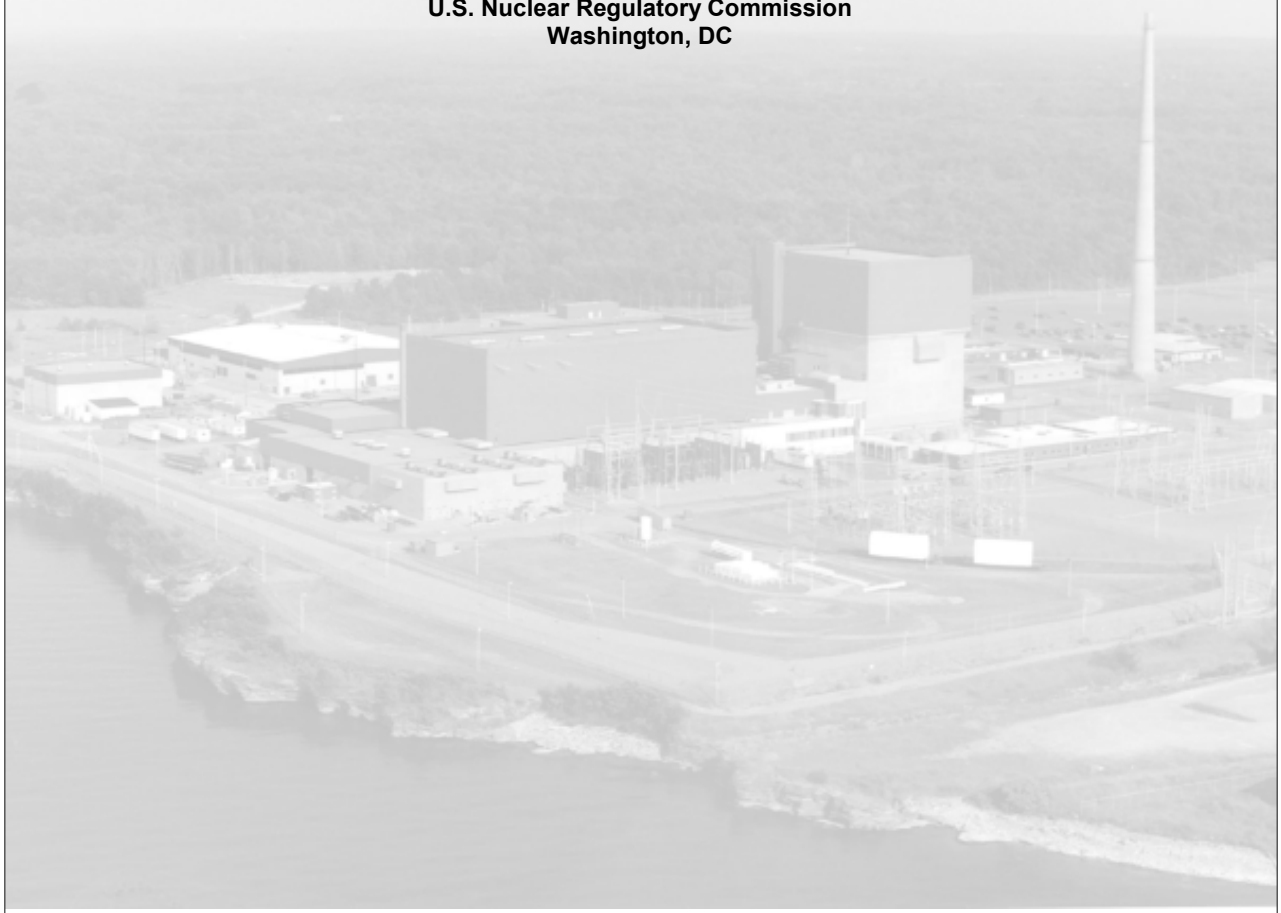
Prepared by:

Office of Nuclear Regulatory Research
Office of Nuclear Material Safety and Safeguards
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC



ABSTRACT

The Office of Nuclear Material Safety and Safeguards and the Office of Federal and State Materials and Environmental Management Programs of the U.S. Nuclear Regulatory Commission have developed a risk-informed decisionmaking (RIDM) framework. The staff can use this framework to supplement its approach to decisionmaking on regulatory relief, safety considerations, and additional requirements. This report outlines the RIDM framework and explains its applicability to a wide range of nuclear material and waste regulatory issues. This report also provides a step-by-step procedure with specific examples in various nuclear material and waste areas to help the staff consistently and effectively apply a risk-informed approach on a case-by-case basis for regulatory decisionmaking.

FOREWORD

This document contains guidance on how to make appropriate risk-informed regulatory decisions for nuclear material and waste applications. This risk-informed decisionmaking (RIDM) framework can be used on a case-by-case basis for activities conducted by the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards (NMSS) and Office of Federal and State Materials and Environmental Management Programs (FSME). Periodic modifications can be made to this guidance to incorporate lessons learned by the staff. Proposed modifications can be reviewed by persons or committees representing a wide range of technical and application areas. Thus, this report should be a living document with future additions and changes to be incorporated as appropriate.

Staff should apply a process to identify, evaluate, and recommend specific regulatory decisions that would benefit from a risk-informed approach. The selection of candidate applications should be based on the benefits and feasibility of applying such an approach.

Candidates for risk assessments are expected to be regular, ongoing regulatory tasks and not special additional studies. The staff usually responsible for the regulatory task will conduct the assessment, but the assessment can be supplemented by risk experts familiar with this document. These experts can use information from the performing organization to carry out the specialized analyses associated with the process. The responsibility for documenting the normal regulatory outcome of the application, such as a safety evaluation report, would reside with the regular line organization performing the application. If the risk information forms a part of the basis for regulatory actions, it should be documented as part of that action. All personnel involved will be expected to contribute changes or supplements to the method, as necessary.

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. For example, complex situations involving competing tradeoffs among a number of factors, such as various risks and costs, could benefit. The guidance suggests two specific decision algorithms. These two algorithms apply to changes to regulatory requirements (i.e., rules or license conditions). Staff could apply these algorithms to a variety of ongoing regulatory work, such as the following:

- proposed rulemaking to impose new requirements directed at improving safety
- proposed additional license conditions directed at improving safety
- proposed rules or license conditions directed at increasing effectiveness, while continuing to maintain safety
- proposed exemptions or changes to existing regulations or license conditions that might cause small increases in risk
- new information raising a question as to whether a specific activity or design is acceptably safe

- events or information for which the safety significance is unclear
- license applications or amendments for facilities, devices, activities, or processes involving hazards or safety designs that differ significantly from those currently regulated
- risk information relevant to license applications for which existing guidance is silent

The NMSS/FSME staff has already incorporated any available risk information in making regulatory decisions. This document provides a structured guidance to risk assessment and also serves as a reference to other existing guidance. The RIDM process considers many factors in addition to risk. This guidance attempts to provide an integrated consideration of most of these factors. An effort has been made to make these methods, to the extent they apply to NMSS/FSME, consistent with existing applicable NRC policies and guidance, in general, and those pertaining to regulatory analysis, in particular.

Together, NMSS and FSME regulate a wide variety of activities. The methods in this guidance have been tested in pilot studies on a few of these activities. Thus, to ensure continual improvement, these methods and guidelines would benefit from additional testing and modification through a process of candidate applications.

Staff from the Office of Regulatory Research (RES) considered the comments and recommendations provided in the related letter from the Advisory Committee on Nuclear Waste and Materials (ACNW&M), dated May 2, 2006, in Revision 1 of this guidance. As a result, the RES staff made the following modifications in this revision of the RIDM document:

- provided the logic description for using the screening criteria to identify an applicable regulatory issue
- converted the probability of quantitative health guideline (QHG) for latent cancer fatality to dose per year for an individual public
- converted the probability of QHG for latent cancer fatality to dose per year for a worker
- added an example and a discussion on risk-informing activities for fuel cycle facilities

This revision also reflects feedback received as a result of reviews by staff from RES, NMSS, FSME, and the Office of Nuclear Reactor Regulation. As a result, this revision of the RIDM document includes substantial changes to the following sections:

- Executive Summary
- Section 4.2.2, “Consideration of New Requirements”
- Section 6, “Risk Communication”
- Appendix J, “Applying the RIDM Methodology to Fuel Cycle Facilities”
- Appendix K, “Issue Characterization”

- Appendix L, “Defining Alternative Actions”
- Appendix M, “Initial Risk Assessment”
- Appendix N, “Assessing the Impact of the Issue on Defense in Depth”
- Appendix O, “Assessing the Impact of the Issue and Alternative Actions on Safety Margins”
- Appendix P, “Reaching Consensus on a Recommendation”

Since NMSS and FSME intend to use the revised RIDM document for future applications on a case-by-case basis, it is important that the document remains a living document and that it is updated periodically to factor in any additional insights gained from its application. Future revisions of the RIDM document should consider the following potential topics:

- an algorithm for performing risk-informed inspections
- an algorithm for license reviews
- detailed risk assessments in support of rulemaking activities (e.g., development of regulatory requirements for reprocessing and nonreactor facilities)
- lessons learned from operating events
- comments from the NMSS/FSME staff for revising the RIDM document
- comments and recommendations from ACNW&M, the Commission, and other NRC management
- comments and recommendations from the Office of Management and Budget

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EXECUTIVE SUMMARY

The objective of this risk-informed decisionmaking (RIDM) guidance document is to provide guidance to the staff of the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards (NMSS) and Office of Federal and State Materials and Environmental Management Programs (FSME) on making appropriate risk-informed decisions for nuclear material and waste. The NRC staff designed this guidance document specifically for NMSS/FSME applications. All relevant attributes should be considered and communicated, including risk, when making risk-informed regulatory decisions. This guidance document aims to achieve the following objectives:

(1) Provide a step-by-step procedure on how to make risk-informed regulatory decisions.

(2) Suggest quantitative health guidelines (QHGs) for acute and latent fatality and injury for both public individuals and workers. The QHGs define the negligible risk levels, below which resources generally should not be used to reduce a risk contributor.

(3) Provide three regions of risk (unacceptable, tolerable, and negligible) for consideration in analyzing risk information and making regulatory decisions.

(4) Discuss how to apply this RIDM methodology to nuclear material and waste regulatory applications.

Since this guidance document is only intended to familiarize NMSS/FSME staff with the risk-informed process and when it should be applied, actual application of the process to complex situations will normally require the assistance of specialists in risk assessment and decisionmaking techniques.

Appendix A provides a glossary of the terms presented in this report.

ACKNOWLEDGMENTS

This document was produced as a joint effort by staff from the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards (NMSS) Risk Task Group (RTG) (2000–2004), the Office of Nuclear Regulatory Research (RES), and Brookhaven National Laboratory (BNL). Staff from all divisions of NMSS reviewed and provided extensive comments on the earlier drafts of this document. The NMSS Risk Steering Group, which includes representation from each of the NMSS divisions, as well as from other NRC offices, including the Office of the General Counsel and the Office of Nuclear Reactor Regulation, offered insightful direction and input.

The following staff participated in preparing the draft risk-informed decisionmaking (RIDM) document dated May 11, 2005:

NMSS RTG

Christiana H. Lui, Dennis R. Damon, James A. Smith, Albert Wong, Jessica Shin, Kimberly A. Gruss, Raeann M. Shane, Terry Brock, Mary Adams, Michael Raddaz, and Shamica Walker

RES

Alan Rubin and Edward Chow

BNL

M. Ali Azarm, Robert Bari, Edward J. Grove, Charles Meinhold, and Vinod Mubayi

Lead Reviewers from NMSS Staff

Patti Silva, Mike Waters, Chris McKenney, John Lubinski, Kevin Ramsey, Hans Arlt, Dennis Galvin, Chris Grossman, Lydia Chang, Joe DeCicco, Patricia Rathbun, and Kim Hardin

In response to a user need request from NMSS, RES produced Revision 1 of the draft RIDM guidance document. To obtain important risk insights and diverse views from those who have been using the risk-informed approach for regulatory decisionmaking, staff members from various NRC offices reviewed and commented on the RIDM guidance document. As a result, comments from the reviewers were incorporated during the revision process.

The following NRC staff participated in preparing Revision 1 of the draft RIDM document:

RES

Edward Chow, Michelle González, Mary Drouin, and Ronaldo Jenkins

NMSS

Dennis Damon, Keith Compton, and Kevin Morrissey

Office of Federal and State Materials and Environmental Management Programs

Joseph DeCicco and Chris McKenney

Office of Nuclear Reactor Regulation

Steven Laur

ABBREVIATIONS

ACNW&M	Advisory Committee on Nuclear Waste and Materials
ACRS	Advisory Committee on Reactor Safeguards
AIChE	American Institute of Chemical Engineering
ALARA	as low as is reasonably achievable
BNL	Brookhaven National Laboratory
BEIR	Biological Effects of Ionizing Radiation (Committee on)
BHA	barrier/hazards analysis
CCDF	complementary cumulative distribution function
CDF	core damage frequency
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
FMEA	failure modes and effects analysis
FSME	Office of Federal and State Materials and Environmental Management Programs
HAZOP	hazard and operability analysis
HLW	high-level waste
HRA	human reliability analysis
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IE	initiating event
IPEEE	individual plant examination of external events
ISA	integrated safety analysis
ISFSI	independent spent fuel storage installation
ISL	in situ leach
km	kilometer
LCF	latent cancer risk
LERF	large early-release frequency
LLW	low-level waste
LTR	lower tolerable risk region or License Termination Rule
LTS	Licensing Tracking System
mrem	millirem
MSHA	Mine Safety and Health Administration
NMED	Nuclear Material Events Database

NMSS	Office of Nuclear Material Safety and Safeguards
NPP	nuclear power plant
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
PA	performance assessment
PGE	Portland General Electric Company
PHA	process hazards analysis
PRA	probabilistic risk assessment
PRAM	preclosure risk assessment methodology
PSA	probabilistic safety assessment
QHG	quantitative health guideline
QHO	quantitative health objective
RES	Office of Nuclear Regulatory Research
RG	regulatory guide
RIDM	risk-informed decisionmaking
RTG	Risk Task Group of the Office of Nuclear Material Safety and Safeguards
SER	safety evaluation report
SGPS	Safety Goal Policy Statement for the Operation of Nuclear Power Plants
SSC	structure, system, or component
UF_6	uranium hexaflouride
UTR	upper tolerable risk region
WB	whole body
WISQARS	Web-based Injury Statistics Query and Reporting System

1 OVERVIEW OF A FRAMEWORK FOR RISK-INFORMED DECISIONMAKING IN NMSS/FSME

Risk-informed decisionmaking (RIDM) is the use of risk insights, along with other important information, to help in making decisions. This document aims to put this concept into practice in the materials and waste arenas of the U.S. Nuclear Regulatory Commission (NRC). The document provides a framework of structured decision methods that, when applied properly, can help staff achieve risk-informed (Ref. 1.1) regulation. The basic principles of this framework are (1) that staff should apply fully quantitative risk-informed methods only to appropriate regulatory decisions, and (2) once the appropriate regulatory decision is identified, staff should follow a structured process when performing a quantitative risk analysis. The guidance presented here defines this structured process. Use of this guidance will ensure that all relevant attributes, including risk, are considered in an effective and consistent manner when making risk-informed regulatory decisions for nuclear material and waste applications. This document focuses on supplementing existing NRC guidance on the use of risk information, particularly guidance on regulatory analysis (Refs. 1.2, 1.3). This document is intended to help the staff of the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Federal and State Materials and Environmental Management Programs (FSME) identify when a structured, quantitative, risk-informed process should be followed and to provide a general familiarity with such a process. Actual application of the process to complex situations will normally require the assistance of specialists in risk assessment and decisionmaking techniques.

Protecting public health and safety is a primary NRC objective. Challenges to public health and safety include both normal and accidental exposures to radiation and other regulated hazards. Normal exposures can be planned, minimized, and monitored, but information on the probability and consequence of accidents must come from statistics or risk assessments. Risk information is a technical description of things that can go wrong, the likelihood of those things happening, and the consequences if they were to happen. This information can be both quantitative and qualitative. Risk information can provide a structured presentation of public health and safety knowledge. Methods of risk assessment have become highly developed. Since public health and safety are a primary concern to the agency, risk information is useful for agency decisionmaking. However, risk information can be complex, and regulatory decisions must consider many inputs, such as normal exposures, accident risk, costs, defense in depth, safety margins, and security. When a decision affects multiple attributes, use of a structured process can be helpful.

This chapter provides an overview of the RIDM process for NMSS/FSME applications. Subsequent chapters describe in greater detail the major steps in the process. Section 1.1 briefly discusses the basic concept of RIDM and some of the terminology used, while Section 1.2 contains an overview of the process itself. Section 1.3 provides a list of references.

1.1 Risk-Informed Decisionmaking Concepts

The intent of this section is to briefly discuss what is meant by RIDM. The NRC has defined the phrase "risk-informed decisionmaking" (Ref. 1.1) as follows:

> A "risk-informed" approach to regulatory decisionmaking represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

The concept of a risk-informed approach first evolved in the reactor context. When the term "risk" is used in that context, it typically refers to risk of core damage and to the offsite public from accidents. However, in the materials and waste arenas of NMSS/FSME, risk is often defined more broadly, taking into account both normal and accidental exposures to workers and the general public. Thus, in the NMSS/FSME context, risk-informed guidance involves consideration of normal and accidental exposures to the public and workers.

An important distinction exists between normal and accidental exposures. Normal exposures are those that occur as planned or are expected to occur during the lifetime of a facility. Accidents are unintentional, typically rare, episodic events. Normal exposures may be directly monitored as part of a radiation protection program. Chronic future exposures and rare accidents require some form of risk assessment, usually quantitative. Subsequent chapters will focus, to a certain extent, on accident risk because 10 CFR Part 20, "Standards for Protection against Radiation," regulates normal exposures. However, the proposed algorithms for making risk-informed decisions address both types of risk.

This document uses the term "accident" to refer to all unexpected or unintended exposures. There is no implication that, because an event is referred to as an "accident," the licensee is not accountable for preventing or mitigating it. Furthermore, in this context, the term "accident" does not refer to "design-basis accidents" or other regulatory designations. The term "accident risk assessment" is an attempt to make realistic estimates in support of a risk-informed approach to regulation.

NMSS/FSME regulates a wide variety of nuclear material uses. The risk-informed decision methods presented are intended to be generic—hence, they are widely applicable across the diverse activities regulated by NMSS/FSME. To make the methods generic, these decision methods consider all relevant attributes and not just risk. In any particular category of licensed activity, only a few of these attributes may be important. This guidance document encompasses all so as to be inclusive and generally applicable. The guidance identifies the types of risk to calculate, the criteria to consider, and the methods of integrating risk with other information to provide the kind of insight that is relevant to a particular situation. Such risk-informed decisions should help NRC staff formulate more effective regulatory programs.

1.2 Summary of the Risk-Informed Decisionmaking Process

The staff developed the methods described in this document to facilitate the application of a risk-informed approach to certain regulatory actions. This current guidance continues to be updated as appropriate. Some criteria and methods have been specified fully, whereas others are in a less developed state. However, users can expect the overall process and most of the decision logic to continue basically in the same form. The methods presented herein are applicable to a number of important decision situations encountered in regulatory activities, but they do not cover all possible situations.

Criteria and considerations included in RIDM are not additional regulatory requirements. Rather, the methods for making risk-informed decisions are useful tools to consider in certain situations, for example, a proposed change to regulatory requirements. Such changes can affect a number of important factors, including individual and societal risk. If these impacts are expected to be significant, the staff may find a risk-informed analysis useful. COMSAJ-97-008, "Discussion on Safety and Compliance," dated August 25, 1997 (Ref. 1.2), states the following:

> Since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities (this includes enforcement).

1.2.1 Overall Risk-Informed Decision Process

The guidance in the subsequent chapters is based on an overall risk-informed decision process. This process consists of four major steps:

(1) Define the regulatory issue and preliminary alternative actions.

(2) Decide whether to risk-inform.

(3) Perform risk assessment as needed.

(4) Apply a RIDM method.

Such a process should be carried out as a coordinated team effort involving a number of disciplines and responsibilities. The first two steps, identifying the issue and deciding whether to use a risk-informed approach, should have substantial involvement by staff in the specific regulatory area. Chapter 2 of this document discusses the screening considerations and how they are applied. Step 3, or risk assessment (discussed in Chapter 3) and step 4, decisionmaking (discussed in Chapter 4), often require assistance from specialized risk analysts. Step 3 generates the risk information needed to support the decision methods in step 4. Step 4 applies logic algorithms that consider risk and a number of other factors to develop input to a decision. The output of these algorithms is information indicating which proposed action(s) should be rejected and which one(s) considered. However, step 4 is intended to be in the spirit of a risk-informed approach. That is, even though the logic of the algorithm may indicate a preferred action, it is intended only to inform, not dictate, the decision. Figure 1.1 illustrates the overall process. The process appears as a simple, single-pass

sequence of steps but, in practice, iterations will occur. Information from the risk analysis often helps identify refinements in the proposed action that are more effective than the original. The following sections summarize further the four major steps in the RIDM process.

1.2.2 Step 1: Define the Regulatory Issue and Alternative Actions

The first step in any decisionmaking situation is to clarify the regulatory question or problem. Given a clear statement of the problem, the next typical step is to propose one or more actions that might solve the problem. A typical regulatory situation might be a lack of sufficient information about the safety of a new type of design or facility. Another typical situation might be a proposed change to regulatory requirements or practices to improve effectiveness. These situations may give rise to questions about risk, such as whether the risk is low enough, or what effect a particular action may have on risk. Devising actions that are the best solution to a problem may not be easy. Risk, cost, and other impacts often involve tradeoffs. The challenge is to find the best alternative. To do this, it is often useful to consider a number of alternatives.

Appendices K and L provide additional guidance on the considerations related to issue characterization and defining alternative actions.

1.2.3 Step 2: Decide Whether To Risk-Inform

After step 1, in which the issue is defined and a list of alternative actions formed, step 2 introduces screening considerations. The purpose of screening is to decide whether a risk-informed approach should be used.

There are four screening considerations, which can be placed in two groups. The first group of screening considerations asks whether risk information would be useful or is necessary in making the decision to support the strategic objective or one or more of the goals in the agency's Strategic Plan (Ref. 1.4). If risk insights cannot be used to support the strategic objective of providing excellence in regulatory actions that are open, effective, realistic, and timely, a risk-informed approach is not necessary. The second group of considerations asks whether developing and using the risk information is feasible, cost effective, and not precluded by other considerations. If risk information is relevant, but cannot be provided because of feasibility or cost, the decision still must be made using another framework—perhaps a less structured or quantitative process. Chapter 2 provides detailed guidance for applying the four screening considerations.

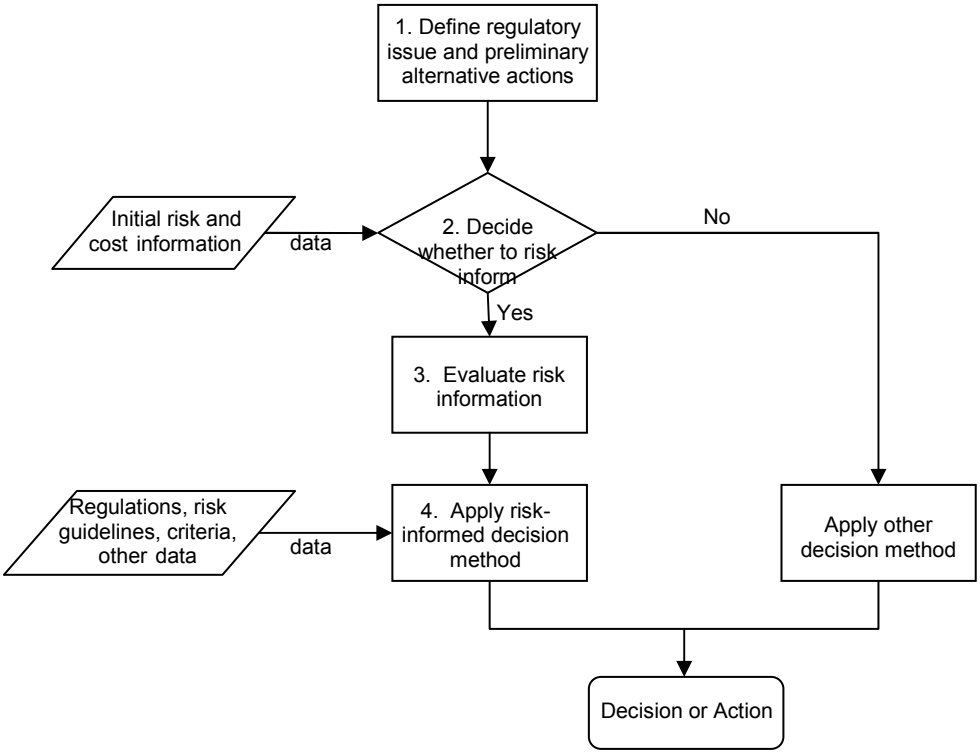

Figure 1.1. Overall Risk Assessment Process

1.2.4 Step 3: Perform Risk Assessment As Needed

Step 3, performing the risk assessment, consists of producing the risk information needed to apply the applicable decision method in step 4. The initial task in this step is to determine the scope of the risk assessment. This amounts to identifying what risk metrics need to be calculated and what level of quality and detail needs to be provided. Some of the needed risk information may already exist or a simple risk analysis may be sufficient. The risk assessment must be forward looking, in that the decision method to be used in step 4 must be identified in advance. This is because different decision methods in step 4 require the calculation of different risk metrics in the risk assessment.

The degree of completeness, applicability, and scientific detail in the risk assessment is often referred to as risk assessment quality. Quality should be commensurate with the purposes of the decision to be made and may also be influenced by the scope and the level of detail associated with the risk assessment.

It is usually important to quantify the uncertainty in the risk results and to assess qualitative uncertainties in step 3, as well. The risk and uncertainty information generated in step 3 is then used in step 4 to assist in making the decision and evaluating its robustness. Chapter 3 of this document provides guidance on this step of performing risk assessments applicable to NMSS/FSME-regulated activities.

Appendix M provides additional guidance on the considerations related to initial risk assessment.

1.2.5 Step 4: Apply a RIDM Method

The objective of step 4 of the risk assessment process is to provide potentially useful guidance for decisionmaking by considering risk and other relevant factors. The guidance in Chapter 4 provides a structure and logic by which this is done in a consistent manner. The logic, referred to here as "algorithms," does not dictate the decision, but simply provides insight to assist the decisionmaker. There are many different situations in which such a risk-informed decision method could be applied. The current guidance in Chapter 4 addresses the following two specific decision situations and provides an algorithm for each:

(1) exemptions or changes to regulatory requirements that might slightly increase risk
(2) imposition of a new regulatory requirement to reduce risk

NRC guidance documents related to regulatory analysis (Refs. 1.2, 1.3) also address these two types of regulatory decisions. However, when addressing accident risk, this existing guidance is highly oriented to reactors. The guidance in Chapter 4 therefore primarily acts as a supplement to the existing guidance by providing accident risk criteria in a form applicable to NMSS/FSME activities. Chapter 4 also discusses certain factors other than risk that should be addressed when making these decisions.

While additional regulatory situations might also benefit from a risk-informed approach, this document does not provide specific algorithms for these situations. However, the basic principles discussed in Chapter 4 and in References 1.2 and 1.3 can be expanded to devise risk-informed approaches for other situations. For example, these principles might be applied when determining risk significance and using risk insights to prioritize licensing or inspection activities. Chapter 4 does not address guidance for the use of qualitative risk information. Some methods currently in use in NMSS/FSME, such as integrated safety analyses (ISAs), produce qualitative risk information. Such information is also useful in applying a risk-informed approach to regulatory actions.

1.2.6 Decision Algorithms

This discussion provides a general perspective on the decision algorithms used in step 4 of the RIDM process (Figure 1.1). Chapter 4 offers a detailed description of the actual decision algorithms. Decision algorithms are simply a set of rules that can be followed to determine a preferred set of decision alternatives. Decision alternatives are typically different regulatory actions that could be taken in a given situation. In the simplest case, two alternatives exist—to take a single proposed regulatory action or to take no action. More often, there are several reasonable alternative actions, including the no-action alternative.

In most situations, the proposed actions affect multiple factors. Such factors might include risk to individual members of the public, risk to individual workers, defense in depth, safety margins, total health impacts on affected populations, total cost impacts, security impacts, environmental impacts, regulatory requirements, and Commission policies.

The decision algorithms described in step 4 treat these factors as either (1) mandatory conditions or (2) individual qualitative contributors to a net total impact. In the first case, certain factors, including risk to individuals, are evaluated and compared directly to any and all regulatory requirements and Commission policies that must be met. These criteria are thus mandatory conditions. Examples include adequate defense in depth and adequate safety margins. For other factors that may involve nonquantifiable considerations, regulatory requirements reveal the applicable criteria. Reference 1.3 provides some guidance for mandatory conditions, but definitive quantitative criteria are not always provided. Chapter 4 also discusses some of these conditions.

The annual limits on dose to the public and workers from routine exposures as outlined in 10 CFR Part 20 are one example of a set of mandatory conditions applicable to individual routine risk. Analogous limits for accident risk are not common in the regulations. However, as indicated in Chapter 4, a logic similar to the annual limits in 10 CFR Part 20 can apply. For example, if a regulatory action were to result in an accident risk to individuals that is too great, that may be sufficient grounds not to take the action. Chapter 4 refers to this concept as "unacceptable risk."

Another criterion indicating that no action should be taken is negligible risk to individuals. Chapter 5 discusses accident risk guidelines defining such levels of risk. These values represent very low risk, relative to U.S. average fatality risks. The decision algorithm in Chapter 4 for new regulatory requirements uses these risk guidelines to indicate when new requirements are unlikely to be justified. That is, if the staff proposes a new requirement to lower accident risk, but its effect on risk would be negligible, the agency might choose not to pursue the proposal. The staff provided guidelines for both workers and the general public. In some areas regulated by NMSS/FSME, worker accident risk is a primary concern. The base values for these guidelines, for negligible accident risk, proposed for evaluation, are as follows:

(1) Public individual risk of acute fatality (QHG 1) is negligible if less than or equal to 5×10^{-7} fatality/yr.

(2) Public individual risk of latent cancer fatality (LCF) (QHG 2) is negligible if less than or equal to 2×10^{-6} fatality/yr or 4 mrem/yr.

(3) Public individual risk of serious injury (QHG 3) is negligible if less than or equal to 1×10^{-6} fatality/yr.

(4) Worker individual risk of acute fatality (QHG 4) is negligible if less than or equal to 1×10^{-6} fatality/yr.

(5) Worker individual risk of LCF (QHG 5) is negligible if less than or equal to 1×10^{-5} fatality/yr or 25 mrem/yr.

(6) Worker individual risk of serious injury (QHG 6) is negligible if less than or equal to $5x10^{-6}$ fatality/yr.

In response to a recommendation by the Advisory Committee on Nuclear Waste and Materials (ACNW&M), the latent cancer QHG values, which are in units of fatalities per year, can be converted into equivalent doses per year by using the International Commission on Radiological Protection (ICRP) conversion factors of $5x10^{-4}$ fatalities per rem for the public and $4x10^{-4}$ fatalities per rem for workers. The ACNW&M provided its review findings of the RIDM guidance document in a letter dated May 2, 2006, to the Commission Chairman (Ref. 1.3).

The staff is considering other approaches for expressing such guidelines as part of the case-by-case evaluation process. To draw risk insights for decision considerations, the staff needs a full range of reference levels for various NMSS/FSME-regulated areas because each area poses different types of safety issues. These issues may include routine doses, chronic exposures, and potential accident risk.

The second use of risk and other attributes occurs in value-impact analysis. Value-impact analysis does not compare each attribute individually to its criterion. Instead, it evaluates the net impact of all attributes together. The attributes include costs as well as public health and safety. The output is a net impact score for each proposed alternative, relative to the no-action alternative. The score indicates which action would produce the highest benefit. This analysis is often helpful when proposed actions have both beneficial and adverse impacts. References 1.5 and 1.6 provide NRC guidance for performing value-impact analysis, including a list of attributes to consider. Appendix B provides a brief summary of this type of analysis.

The approach for regulatory decisionmaking used in NMSS/FSME for nuclear material and waste applications is similar to the approach used by the Office of Nuclear Reactor Regulation (NRR) for reactor applications (Refs. 1.7, 1.8). For regulatory decisionmaking in reactor applications, NRR has been using three-region risk diagrams with acceptable guidelines for core damage frequency (CDF) and large early release frequency (LERF). For regulatory decisionmaking in NMSS/FSME applications, the NRC is using three-region risk diagrams with quantitative risk guidelines for a public individual and a worker.

To translate a risk-informed decision to an effective action, a risk communication plan is needed to be developed as one of the early activities. Chapter 6 provides a discussion on how to develop a risk communication plan, document the risk-informed decision, and communicate the decision to the internal and external stakeholders.

1.3 References

1.1 U.S. Nuclear Regulatory Commission, “White Paper on Risk-Informed and Performance-Based Regulation,” SECY-98-144, June 22, 1998.

1.2 U.S. Nuclear Regulatory Commission, “Discussion on Safety and Compliance,” COMSAJ-97-008, August 25, 1997.

1.3 U.S. Nuclear Regulatory Commission Letter from Michael T. Ryan, Advisory Committee on Nuclear Waste to Chairman Diaz, “Risk-Informed Decisionmaking for Nuclear material and Wastes,” May 2, 2006.

1.4 U.S. Nuclear Regulatory Commission, “FY 2008-2013 Strategic Plan," NUREG-1614 Volume 4, February 2008.

1.5 U.S. Nuclear Regulatory Commission, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NUREG/BR-0058, July 2000.

1.6 U.S. Nuclear Regulatory Commission, “Regulatory Analysis Technical Evaluation Handbook,” NUREG/BR-0184, January 1997.

1.7 U.S. Nuclear Regulatory Commission, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Regulatory Guide 1.174, Revision 1, November 2002.

1.8 U.S. Nuclear Regulatory Commission, “Integrated Risk-Informed Decisionmaking Process for Emergent Issues,” LIC-504, Revision 2, February 12, 2007.

2 DECIDING WHETHER NMSS/FSME SHOULD USE A STRUCTURED RISK-INFORMED PROCESS

2.1 Introduction

This chapter focuses on identifying regulatory issues that would benefit from the application of risk-informed process and the screening considerations that can help staff determine whether they should use such an approach. The screening considerations as documented in Ref. 2.1 were tested on a spectrum of NMSS/FSME activities and were found to be effective for determining the appropriateness of applying a risk-informed approach to regulatory issues.

The screening considerations are a series of four questions to help determine whether to use a structured risk-informed approach. These questions examine both the *benefits* and *feasibility* of implementing such an approach. They are intended to prompt thought and elicit professional judgment on whether to apply a risk-informed approach. They are not intended as a strict "yes/no" checklist to a decision.

2.1.1 Applying Risk Analysis to Nuclear Material and Waste Activities

The NRC policy on implementing risk-informed regulation was expressed in the 1995 Policy Statement (Ref. 2.2) on the use of Probabilistic Risk Assessment (PRA) methods in regulatory activities. This statement called for an increase in the use of PRA technology in all regulatory matters, consistent with state-of-the-art PRA methods and data. The use of PRA technology should complement NRC's deterministic approach and support NRC's traditional defense in depth philosophy. The concept of "risk-informed regulation" is the one advanced in the NRC White Paper on the subject (Ref. 2.3).

The Commission recognized that a single approach for incorporating risk insights into the regulatory process would not be appropriate, given the widely varying use of nuclear material in reactors, industrial applications, and waste disposal facilities. Accordingly, several activities in the then NMSS between 1998 and 2001 (Refs. 2.4 – 2.11) led to the development of the screening considerations discussed here.

2.1.2 Risk Information and Regulatory Decisionmaking

The screening considerations, taken together, make up one important element in the process associated with risk-informed regulatory decisionmaking. Figure 1.1 illustrates the process to be used in the nuclear material and waste arenas.

To begin, staff should identify the regulatory issues or action alternatives for a risk-informed approach. The next step is to develop or collect the information needed to address each of the screening considerations; that is, information needed to address the suitability of pursuing the RIDM approach.

After applying the screening considerations, staff should make a feasibility check. If, at this point, the issue is screened out for a structured risk-informed approach, then the outcome should be recorded and the reasons documented (for further information, refer to Chapter 4).

If the issue is screened in for a structured risk-informed approach, the next step is to carry out or adapt an appropriate risk assessment suitable to the regulatory issues in question and to document the reasons for doing so. We will discuss suitable assessments in more detail in Chapter 3. At this juncture, it is important for staff to determine the depth and scope of the analysis required, identify the population at risk, and determine risk metrics. If approved risk guidelines relevant to the risk metrics are available, staff should identify those guidelines in order to compare the risk results to the guidelines in arriving at the decision. In using risk results to make the decision, staff should identify competing risks and, to the extent possible, review other related cases and studies.

Applying a risk-informed approach to the regulatory framework may involve changing regulations through rulemaking. However, it will more likely provide additional insights to aid the decisionmaking in licensing, inspection, and enforcement. Risk information is also used in performing regulatory analysis of an alternative action, as documented in NUREG/BR-0184, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission" (Ref. 2.12). Further development of risk applications in the materials and waste arenas can help bring risk insights to bear on the process of regulatory analysis.

2.2 Defining the Regulatory Issue and Alternatives

As part of this screening process, it is useful to clarify what regulatory question, problem, issue, or decision needs to be made. A clear regulatory issue statement would also help define the type, scope, and depth of the analysis needed. It is often useful to identify a preliminary set of alternative actions the agency may take. Insights derived from risk assessment and other information may clarify which are the more effective alternatives. Eventually, it becomes necessary to evaluate the risk and other impacts of each of these alternatives to provide insight as to a preference.

Actions to address a regulatory problem can have multiple impacts. Some risks may decrease, others increase; the actions may also affect licensed activities in other ways. Hence, identifying actions that would be most effective may not be simple and may require management guidance.

Additional guidance on the considerations related to issue characterization and defining alternative actions are provided in Appendices K and L, respectively.

2.3 *Screening Considerations*

This section discusses the RIDM screening considerations and identifies the factors that need to be addressed when applying them to regulatory issues or action alternatives. Examples of the application of screening considerations are provided in Appendix C.

The four questions used to examine both the *benefits* and *feasibility* of implementing a risk-informed approach are listed in Exhibit 2.1.

The screening considerations were first issued in 2000 as draft screening *criteria* and tested through a series of case studies (Refs. 2.1, 2.11). These case studies were retrospective looks at a spectrum of activities in the materials and waste arenas that had elements of a RIDM process. One notable change that resulted from the case study program was that the *criteria* became *considerations*. This meant that a strict yes/no logic need not be followed in using the outcomes from the questions posed in the considerations. Rather, the screening considerations should be seen as guidelines to facilitate decisions by NRC management and staff. Ref. 2.1 provides a detailed discussion of how the criteria became considerations.

The four screening considerations can be separated into two groups. The first group, consideration 1, relates to the benefits (as embodied in the Commission's Strategic Plan) that can be derived from using the RIDM approach. The second group, considerations 2 through 4, addresses whether the risk-informed approach is feasible. A regulatory application is screened in if the RIDM process could be both beneficial and feasible.

To use this screening method, it is necessary to state clearly the regulatory decision or action alternatives under consideration. This will permit a clearer evaluation of the possible benefits of the risk information with respect to consideration 1. One should answer all the screening consideration questions, regardless of whether the issue is screened in before all the questions are addressed. A thoughtful response to all the questions could help communicate all the benefits of implementing a proposed risk-informed regulatory action such as the RIDM process. The amount of time spent on answering the screening questions should be measured in hours, not days.

2.3.1 Discussion of Screening Considerations Based on Benefits

The screening considerations related to the benefits of a risk-informed approach are based on NRC's strategic objective of providing excellence in regulatory actions that are open, effective, realistic, and timely as described in the Strategic Plan. Some of the factors that need to be addressed and the important questions that should be considered when responding to the screening considerations are discussed in Exhibit 2.1. The questions are intended to prompt thought and elicit professional judgment and are not to be used as a strict dichotomous "yes/no" checklist guiding the decision.

Exhibit 2.1. Screening Considerations

BENEFIT OF IMPLEMENTING A RISK-INFORMED REGULATORY APPROACH

(1) Could a risk-informed regulatory approach help address the Commission's strategic objective in the NRC's Strategic Plan?

FEASIBILITY OF IMPLEMENTING A RISK-INFORMED REGULATORY APPROACH

(2) Do data and/or analytical models of sufficient quality exist, or could they reasonably be developed to permit the application of risk information to a regulatory activity?

(3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, an applicant or licensee, or the public, and provide a net benefit?

(4) Would any other existing factor(s) limit the utility of implementing a risk-informed approach?

If the RIDM approach is both beneficial and feasible for a regulatory application, it is screened in.

Screening Consideration 1 - Strategic Plan Compliance

Could a risk-informed regulatory approach help address the Commission's strategic objective in the NRC's Strategic Plan (Ref. 2.15)?

In applying this screening consideration, one should assess whether risk information can help meeting the NRC's strategic objective of providing excellence in regulatory actions that are open, effective, realistic, and timely as described in the Strategic Plan. Exhibit 2.2 outlines the major components of this plan that are applicable to NMSS/FSME.

Exhibit 2.2. NRC Strategic Plan (FY 2008-2013)

Strategic Objective

Enable the use and management of radioactive materials and nuclear fuels for beneficial civilian purposes in a manner that protects public health and safety and the environment, promotes the security of our nation, and provides for excellence in regulatory actions that are open, effective, efficient, realistic, and timely.

Strategic Goals

Safety - Ensure adequate protection of public health and safety and the environment.

Security - Ensure adequate protection in the secure use and management of radioactive materials.

Application of screening consideration 1 does not imply that the regulatory activity must be applicable to each individual strategic objective and goal. Applicability to only one can be deemed sufficient. For regulatory activities related to safety, there are three main factors or questions:

(1) Does the activity's current safety level need improvement?

(2) If the activity is safe enough, could other aspects of the regulatory framework be improved while still maintaining safety?

(3) Would risk information be useful in assessing a new activity's safety level?

The first question relates to whether the current facility or activity complies with established standards or limits. There is a general presumption that adherence to the rules and regulations of Title 10 of the *Code of Federal Regulations* assure adequate protection of the public. However, the following issues can give rise to a safety question:

- An unresolved question, as to physical behavior or data, that bears on safety performance;
- A concern that there may be unrecognized or unevaluated hazards or potential accidents;
- New information (for example, a failure event) indicating that the risk from known hazards is greater than previously assessed; and
- The uncertainty in risk, based on current analyses and information, is too large and needs to be reduced.

The second question arises if an action or a change modifies the current situation or activity. These situations can involve changing the existing regulations or their implementation and may lead to cases that challenge the presumption of adequate protection. Regulatory Guide(RG) 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Ref. 2.13) addresses one class of such events; namely, requests for changes to the current licensing basis for nuclear power reactors that might result in increased risk. In such situations, risk assessments may be needed to address the criteria given in RG 1.174 for assessing the acceptability of the proposed change. Of more immediate interest to NMSS/FSME is the intriguing situation that is illustrated by the Trojan Reactor Vessel transport exemption (Ref. 2.14). In that case, an exemption from the regulations resulted in an activity that was a substantial reduction in the overall risk as well as cost. This benefit might not have been realized had staff not performed a systematic quantitative risk assessment. Applying risk information can help evaluate whether safety will continue to be maintained after the change is implemented.

The third type of question can arise from the introduction of new safety technologies, or the application to license a new type of nuclear device or facility not anticipated in the current regulatory system. Such situations may benefit from a review using systematic risk assessment methods to see if new types of hazards or accidents exist, and to provide assurance that all are adequately addressed. Improved risk assessment, including quantification of uncertainty, may help to resolve such issues.

In applying this screening consideration, one should assess whether risk information can help to streamline processes and improve consistency, while still keeping the focus on safety. The main factors to be addressed in this screening consideration are as follows:

- Are there aspects of the regulatory framework that could be streamlined through the use of risk information?
- Could the use of risk information produce more consistent decisions among NRC staff?

The first question ensures that regulations are open, effective, realistic, and timely. For example, the case study on the Trojan reactor vessel package shipment (Ref. 2.14) showed that applying risk information to the review of an exemption from the regulations streamlined the NRC staff's decisionmaking process.

The second question ensures consistency across different applications, while keeping the focus on safety. By identifying all relevant risk metrics, and by setting risk-based standards and goals, a RIDM approach may help to enhance consistency and completeness. Such standards and goals can facilitate rapid staff decisionmaking and thus improve efficiency and response time. Finally, risk information can be used to optimize the allocation of staff effort and maintain a focus on those features and issues most important to safety.

If the regulatory application under review may reduce the regulatory burden, the following points should be considered:

- Could risk information be used to change regulations or policy so that the regulatory burden is more consistent with the magnitude of the risk?
- Could risk information be used to change NRC licensing or inspection policies to focus the most effort on those areas that have the biggest safety impact, while still maintaining overall safety?

The first question relates to the use of risk information to assess whether the regulatory burden is consistent with the hazard of the activity. This may be a simple or complex question in the case of specific proposals to lessen or eliminate a requirement. Licensees are often able to provide applicable data on the impact of regulatory burden. On the other hand, some proposed changes result in a mixture of both added and reduced burdens that require analytical effort to determine net impact. It is important to recognize that a burden could also be placed on States, other entities, and the general public (taxpayers) (e.g., clean-up of a contaminated site when the risk is low).

The second question relates to using risk information in such a way that NRC licensing or inspection policies are focused on those areas that have the largest safety impact. Proper risk allocation would result in a graded approach that allocates resources to licensing and inspection of systems, structures, components, and procedures in a way that optimizes averted risk while maintaining overall safety.

In evaluating applications where risk information can be used to clarify decisions, implement a transparent process, and make defensible decisions, several factors should be considered:

- What is the existing public perception and acceptance of risk in the subject area?

- Could risk information be used to provide a better understanding of the basis for a decision?
- Would risk information make staff decisions clearer or more defensible, or provide greater transparency to our process?

Generally, a risk-informed approach provides data and information about a set of options and an objective basis for choosing a particular option. There is a reasonable assumption that this would provide more and better information to support the underlying rationale of an agency decision. In principle, it could thus lead to decisions that are more transparent and more defensible.

Risk assessment results often clarify why the system of regulatory requirements provides adequate safety. They not only state how safe a situation is, but identify how various features limit the risk and provide assurance that all paths to adverse consequences have been adequately addressed. Clarity and completeness in the staff's knowledge of the safety basis can enhance its communications even with those less informed as to the technical details.

2.3.2 Discussion of Screening Considerations Based on Feasibility

The remaining three screening considerations essentially relate to the feasibility of applying risk information to the proposed regulatory activity.

Screening Consideration 2 - Availability of Data and Models

Are there data and/or analytical models of sufficient quality, or could they be reasonably developed, to support the application of a risk-informed approach to a regulatory activity?

The factors involved in this screening consideration all relate to the amount and quality of risk information available:

- What risk information is currently available in the subject area?
- Have risk studies been done?
- Do the studies cover the relevant hazards of the activity (e.g., the isotopes involved, the quantities, physical form, and chemical hazards of those isotopes)?
- Are the studies complete and up-to-date (i.e., do they reflect the current configuration of the facility and/or activity)?
- Do the studies reflect the current regulatory environment?
- What additional studies would be needed to support decisionmaking and at what cost?
- If computer codes are necessary, are those codes available, could they be modified, or would they have to be developed?

These factors are concerned with the inventory and pedigree of the information that is available for the activity under consideration. Some judgment has to be made regarding its applicability,

completeness, and suitability in order to decide whether further information is needed, such as data, analytical models, and computer codes, as well as the time frame required and the costs.

Screening Consideration 3 - Reasonable Implementation Costs

Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, an applicant or licensee, and/or the public, and provide a net benefit?

In applying this consideration, one should consider the net benefit of a risk-informed approach; (i.e., whether the benefits exceed the cost). The factors involved in this screening consideration are:

- What is the societal benefit of the regulated activity?
- What is the net benefit from applying a risk-informed approach to the activity; in other words, would it improve public health and safety, improve protection of the environment, improve communication, and improve regulatory efficiency. Would it do all this while assuring the same safety level, and would it also result in a cost-savings?

The concept of net benefit is defined in NRC's Regulatory Analysis Guidelines (Ref. 2.12) as the algebraic difference between the benefits of an action, or alternative, and the costs of its implementation when both are expressed in the same units. For instance, if the benefits are expressed in averted doses, they are converted to monetary units at $2000 per avoided person-rem. It is useful to realize that screening considerations 2 and 3 are, in one sense, closely related. If insufficient data and models are currently available and new information has to be developed, the resources that are needed to obtain this information have to be compared to the benefits that the information will provide. Thus, net benefit is the criterion for implementing a risk-informed approach that can consist of various methods, differing in cost and quality and ranging from a scoping study to a detailed risk assessment. However, it is not expected that a full cost-benefit analysis be performed during the screening.

Screening Consideration 4 - Existence of Other Precluding Factors

Would any other existing factor(s) limit the utility of implementing a risk-informed approach?

This screening consideration determines whether other precluding factors, such as legislative or judicial decisions, long-standing agency policy issues, or social considerations would limit the implementation of a risk-informed approach.

Legislation (proposed or enacted) or judicial decisions might preclude alteration of the current regulatory approach. For example, other agencies, such as Agreement States, may be involved in regulating the licensees. The licensee could also fall under multiple jurisdictions. There could also be issues of agency policy, or current or emerging social considerations, that may become an obstacle to using risk information. Similarly, another potential obstacle is significant adverse stakeholder reaction, because of a real or perceived safety concern regarding the proposed risk-informed approach. These factors need to be evaluated for their impact on NMSS/FSME-regulated activities.

2.4 Disposition of Screened-Out Regulatory Issues

If an issue is screened out after the determination that a RIDM approach is not appropriate, other decisionmaking means should be used. These could include a review of license requirements and the impact of the proposed change to these (i.e., dose, public health and safety, environmental protection), or impact on regulatory oversight effectiveness. Additional discussion on the risk-informed decision methodology is provided in Chapter 4 to guide those issues that are screened in to follow the RIDM process.

2.5 References

2.1 U.S. Nuclear Regulatory Commission, "Risk-Informing the Material and Waste Arenas: Integration of Case Studies and Related Risk Assessments in the Nuclear Material and Waste Arenas," December 2001.

2.2 U.S. Nuclear Regulatory Commission, "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities: Final Policy Statement," *Federal Register,* Vol. 60, No.158, August 16, 1995.

2.3 U.S. Nuclear Regulatory Commission, "Staff Requirements - SECY-98-144 - White Paper on Risk-Informed and Performance-Based Regulation," March 1, 1999.

2.4 U.S. Nuclear Regulatory Commission, "Risk-Informed, Performance-Based and Risk-Informed, Less-Prescriptive Regulation in the Office of Nuclear Material Safety and Safeguards," SECY-98-138, June 11, 1998.

2.5 U.S. Nuclear Regulatory Commission, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," SECY-99-100, March 11, 1999.

2.6 U.S. Nuclear Regulatory Commission, Draft Screening Criteria, *Federal Register,* 65 FR 14323, March 16, 2000.

2.7 U.S. Nuclear Regulatory Commission, Case Study Plan and Revised Draft Screening Criteria, *Federal Register,* 65 FR 54323, September 7, 2000.

2.8 U.S. Nuclear Regulatory Commission, "Staff Requirements Memorandum - SECY-99-100- Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," June 28, 1999.

2.9 U.S. Nuclear Regulatory Commission, "Transcript of the Public Workshop on Risk-Informing NMSS," Washington, DC, April 25-26, 2000.

2.10 U.S. Nuclear Regulatory Commission, "Transcript of the Public Meeting on the Draft Case Study Plan," Rockville, MD, September 21, 2000.

2.11 U.S. Nuclear Regulatory Commission, “Plan for Using Risk Information in the Materials and Waste Arena,” Case Studies Plan, prepared by the Risk Task Group, ADAMS Accession Number ML003759642, October 27, 2000.

2.12 U.S. Nuclear Regulatory Commission, “Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission,” NUREG/BR-0184, January 1997.

2.13 U.S. Nuclear Regulatory Commission, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Regulatory Guide 1.174, July 1998.

2.14 U.S. Nuclear Regulatory Commission, “Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments,” ADAMS Accession Number ML022130067, February 2002.

2.15 U.S. Nuclear Regulatory Commission, “FY 2008-2013 Strategic Plan," NUREG-1614 Volume 4, February 2008.

3 GUIDANCE FOR CONDUCTING RISK ASSESSMENTS FOR NUCLEAR MATERIAL AND WASTE APPLICATIONS

3.1 Introduction

This chapter provides an overview of methods to perform a risk analysis that would be appropriate to the specific regulatory issue or licensing action. The performance of a risk analysis is one important element in the risk-informing process associated with regulatory decisionmaking. Figure 1.1 in Chapter 1 illustrates the complete RIDM process for the nuclear material and waste arenas. Details on common aspects for all risk assessment methods (e.g., project team, hazard identification/screening, delineation of accident sequences) are discussed in Appendix D.

3.2 Approach

There is no single methodology for performing a risk analysis. Each particular methodology offers specialized schemes and tools for analyzing facilities or processes. However, all methodologies are systematic and tend to provide a disciplined approach to the evaluation of safety or risk. The materials and waste arenas present a wide range of technologies for risk assessment. Some technologies are comparatively complex, whereas others are rather straightforward. This chapter surveys the range of methodologies available and provides guidance on how to select an evaluation approach in a particular problem area. The four broad categories given in SECY-99-100 (Ref. 3.1) are used to define the areas of interest to NMSS/FSME. Some adaptation of these methods to particular cases may be required.

The assessment of risk involves an estimate of both frequency and consequences. Compared with power reactors, materials and waste activities offer a much wider variety, as well as combinations, of frequencies and consequences. Some activities involve continuous exposures with low consequences; others involve low-frequency events with fatal consequences, but to only a very few persons. Only a few facilities are similar to reactors, involving low-frequency events with large numbers of persons potentially exposed to high consequences. Identifying the population at significant risk is a critical part of assessing the risk from NMSS/FSME-regulated applications. NMSS/FSME activities also involve a variety of safety design approaches, many relying on human control. This variability in risk, and in safety design, results in a variety of risk-analysis approaches. However, the fundamental considerations of frequency and consequence are always involved, if only implicitly.

Central to performing a risk assessment is determining the scope and depth of the analysis that would support decisionmaking related to the regulatory issue or licensing action. In some cases, a simplified risk assessment would be warranted. In other situations, sufficient information on risk might already be available in reports and papers. A screening procedure is presented that will help to focus the more in-depth analysis on the events and situations that pose a higher risk.

This chapter provides guidance on a top-level approach to performing a risk assessment in the materials and waste arenas. However, it does not give specific recommendations on how to perform the detailed analysis. Particular methodology options are cited and a recent International Atomic Energy Agency (IAEA) report (Ref. 3.2) 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.

3.3 Grouping NMSS/FSME-Regulated Facilities, Sites, and Devices

3.3.1 Overview of Licensed Facilities

The materials and waste arenas regulated by NMSS/FSME encompass a wide range of technologies, types of facilities, and risks. Not surprisingly, the risks associated with these varying technologies also vary widely. SECY-99-100 (Ref. 3.1) recognized these variations and categorized the NMSS/FSME-regulated activities into four groups (Figure 3.1): (1) activities involving the long-term presence of nuclear material at a planned acceptable level; (2) activities involving the use of casks to safely store and transport nuclear material under both normal and off-normal conditions; (3) activities that involve the physical and chemical processing and possession of nuclear material; and (4) activities involving the use of sealed or unsealed byproduct material.

This categorization is representative of the current NMSS/FSME organization and its regulatory oversight. Although the groups are organized by similar facility types, significant differences also exist. As discussed in SECY-99-100, these differences include the facilities, systems, or devices employed; potential exposure pathways; risks; accident initiators and frequencies; accident consequences; and populations or individuals at risk. Not surprisingly, these differences are the major modeling considerations in the risk evaluation process for each facility group.

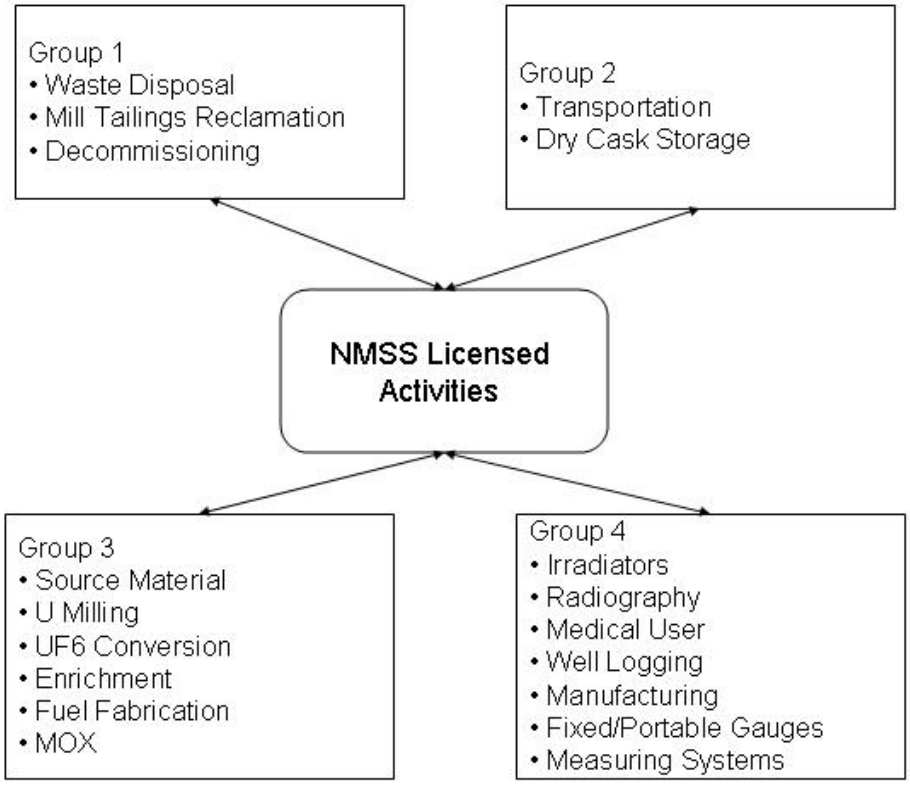

Figure 3.1 Grouping of NMSS/FSME-licensed activities

3.3.2 Description of Facility Grouping

Group 1 comprises facilities designed for the safe disposal of radioactive wastes, as well as those sites that will have residual radioactivity after operations cease. The primary issues and facilities included in this grouping are: the geologic repository for high-level waste (HLW); land disposal of low-level waste (LLW); reclamation of mill tailings disposal sites; and other general site cleanup issues, such as residual site contamination after the decommissioning process.

Group 2 is concerned primarily with issues pertaining to the risks associated with the safe transportation and storage of spent fuel, including dry cask storage.

Group 3 comprises those facilities and issues associated with fuel fabrication, uranium enrichment, and the milling of source material. Uranium mining is not included, since this is not regulated by NRC. Group 3 also encompasses non-nuclear risks, primarily chemical risks, associated with the processes and facilities employed for uranium processing and fuel fabrication. Until recently, these risks were not a main NRC concern, and regulation and oversight were accomplished by working agreements with other agencies such as the Occupational Safety and Health Administration (OSHA), the Mining Safety and Health

Administration (MSHA), and State agencies. Recent studies at Brookhaven National Laboratory (BNL) and the Center for Nuclear Waste Regulatory Analysis (CNWRA) (Ref. 3.4) have highlighted the importance of understanding and managing chemical risks associated with the extraction, processing, and storage of nuclear material.

Group 4 is very broad in nature and encompasses the use of sealed (and unsealed) sources for industrial radiography, irradiators, nuclear medicine, and well logging. This group includes the greatest diversity in terms of the number of sources and users and presents its own unique set of risks, which tend to be dominated by human error. Continuing progress in many fields that rely on these devices highlights the importance of identifying and controlling the unique risks associated with them.

3.4 Risk Assessments

When the need for a risk assessment is identified, various methodology options exist for performing the risk assessment. The choice of method will need to be tailored to the facility or process being assessed, and the desired results (e.g., quantitative, qualitative). This Chapter will describe four specific types of assessments: the PRA, the Integrated Safety Analysis (ISA), the performance assessment (PA), and the barrier/hazard analysis (BHA).

3.4.1 Why Perform Risk Analyses?

Risk analyses may be performed in response to technical and/or regulatory requirements. Regardless of the reason, risk assessments estimate the type and amount of damage or personal injury that may be anticipated from exposure to a specific risk (Ref. 3.5). An example of a risk analysis performed in response to a regulatory requirement would be an Integrated Safety Analysis (ISA). As discussed in NUREG-1513, “Integrated Safety Analysis Guidance Document” (Ref. 3.6), NRC promulgated a revised 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” (Ref. 3.7), on September 18, 2000, that addressed requirements for facilities using special nuclear material. This rulemaking included a requirement that these licensees conduct a specific type of risk assessment, an ISA. The ISA (discussed in Section 3.5.2) would form the basis for the facility's safety program, to ensure adequate controls and systems are in place for continued safe operation. These regulations are applicable to all licensees authorized to possess greater than a critical mass of special nuclear material and engaged in the following: enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that could significantly affect public health and safety. The 10 CFR Part 70 regulations do not apply to gaseous diffusion plants or decommissioned facilities.

In addition to regulatory requirements, a facility operator or regulator may decide to conduct a risk assessment purely for technical or economic reasons, such as for improved design or optimized operation. Such analysis would assist the regulators in assessing the significance and the effects anticipated from these changes. From this information, staff can evaluate various responses to reduce the overall significance of these risks; these could include new or revised regulations, changed inspection and enforcement oversight, process or equipment modifications, or a change in emphasis on operator performance. Risk assessments can be

limited in scope and address a unique or specific process or be all-encompassing and address all the special hazards present at a facility, including nuclear and chemical risks.

3.4.2 Potential Benefits from Performing Risk Analyses

In addition to the specific reason for performing a risk analysis (e.g. regulatory compliance) and the specific tool chosen (e.g, PRA, ISA, Hazard and Operability Analysis (HAZOP), there are many other potential benefits. Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," (Ref. 3.8) encourages the increased use of PRAs to improve safety decisionmaking and regulatory efficiency for reactors. Similar results could be realized for specific NMSS/FSME applications. NRC inspectors may also benefit from such studies by focusing their oversight on the most important aspects of a facility's operation.

Licensees can use risk analyses to support decisions to modify a facility's licensing basis, for example through license amendments or technical specification changes. Licensees and staff can obtain specific information on whether a facility meets current regulations, maintains a defense in depth philosophy, provides sufficient safety margins; and develops performance measurement strategies to monitor change over time. Chapter 4 of this document provides additional information in these areas. When performing the detailed review necessary to support a risk analysis, the licensee may identify regulatory requirements or commitments that may be deemed overly restrictive or unnecessary, or may discover a lack of compliance in some area. Similarly, such an analysis may identify aspects of a design or operational process that require enhanced safety measures. Defense in depth is an important component of power reactor design that, until recently, was not commonly thought of in the NMSS/FSME arena. In a letter to the Commission (Ref. 3.9), the chairmen of the Advisory Committee for Nuclear Waste and Materials (ACNW&M) and the Advisory Committee for Reactor Safeguards (ACRS) observed:

- The treatment of defense in depth for transportation, storage, processing, and fabrication should be similar to its treatment for reactors. Defense in depth for industrial and medical applications can be minimal and addressed on the basis of actuarial information.
- Defense in depth for protecting the public health and environment from HLW repositories is both a technical and policy issue that requires a reasonable balance.
- Since the balancing of compensatory measures to achieve defense in depth depends the acceptability of the risk posed by the activity or facility, risk-acceptance criteria should be developed for all NMSS/FSME activities.

3.4.3 The Use of Expert Judgment in Risk Analysis

Judgment is important on at least two levels of the RIDM process. First, judgment is used in the development of the risk analysis itself; second, it is used by the decision-maker in the decisionmaking process. The decision-maker may not be the analyst and thus, if a decision is being made on the basis of risk analysis information, the decision-maker may not have a good sense of the degree of judgment that was used in the analysis.

Judgment is used in many aspects of the qualitative and quantitative developments of any risk analysis. At present, there is no unambiguous indicator of the degree to which any given risk analysis rests on judgment and of the degree to which it rests on empirical data. The computed risk indices contain quantified tolerance bands. However, these uncertainty bands usually incorporate an imprecisely specified mixture of contributors to uncertainty, including inherent randomness and lack of knowledge. Although it is important for the decision-maker to be aware of the degree to which a risk analysis was dependent on judgment, there is currently no precise way to measure it.

One would expect that the more aware the decision-maker is of the technical nuances of judgment in risk analysis, the more likely it would be that his or her judgment in the decisionmaking process would reflect the judgment used by the analysts. Ideally, results of analysis that are based on judgment should be presented to a decision-maker in a format that is compatible with his or her level of understanding of the technical details. Results of alternative models, assumptions, etc., should be presented in a similar fashion. This information would allow the decision-maker to assess the impact of subjective information on results.

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.

Conservatism (or optimism) can then be applied by the decision-makers in drawing conclusions and taking actions based on the knowledge of the results of the risk analysis.

3.5 Tools to Assess Risks

The purpose of this section is to provide a brief description and overview of several representative risk-assessment techniques. After reading this section, the reader will hopefully understand why a particular assessment methodology is applied to a specific group of facilities. This section does not intend to provide detailed instructions on applying the techniques in the assessment of NMSS/FSME-regulated facilities.

Attachments 2 and 3 to SECY-99-100 identified suggested risk assessment methods for each of the four groups and the potential regulatory use of these methods for specific NMSS/FSME-regulated activities. NRC's PRA Policy Statement provides general guidance on the regulatory uses of risk assessment. Staff can implement this general guidance in many ways. However, as discussed, in each case, staff should address two principal considerations:

(1) What specific use is the staff expected to make of risk insights and risk assessment in the development of regulations and guidance for licensing, inspection, assessment, and enforcement?

(2) What specific use is the licensee expected to make of risk insights and risk assessment in planning and conducting its operations?

In answering these questions, staff must consider numerous facility- and activity-specific factors, such as the hazard and complexity of the activity, the amount of human involvement in the activity, and the technical sophistication of the licensee. For any given facility or activity, staff may find more than one risk-assessment approach suitable. For some, a qualitative use of risk assessment will suffice, whereas others will require a quantitative approach. The authors do not anticipate extensive probabilistic risk studies by each licensee and for each facility. Previously completed risk assessments may be used if available (e.g., NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" and NUREG/CR-6672 for spent fuel transportation). 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.

The methods that will be briefly described in this chapter are Probabilistic Risk Analysis (PRA), Integrated Safety Analysis (ISA), Performance Assessment (PA), and Barrier/Hazard method (BHA).

3.5.1 Probabilistic Risk Analysis (PRA)

PRA is an analytic tool that can be used by both regulators and industry to protect public health and safety. The term "PRA" is used synonymously with Probabilistic Safety Assessments (PSAs). However, a PSA generally deals with safety-related issues, whereas a PRA may deal with both safety and non-safety issues. The scope, level of detail, tools, and methods needed to perform a PSA or a PRA are the same. In Europe, regulators prefer the term PSA because of how they use the results from the analysis with regard to safety decisions. In the US, the NRC prefers the term PRA, because the analysis is a calculation of the "risk" (likelihood and consequences) and not a calculation of safety (even though the results from the PRA may be used in safety decisions). In the remainder of this paper, the term "PRA" will be used to denote both concepts. Staff can use PRAs to compute the probability of health, environmental, and economic consequences of events caused by equipment or human failure.

The birth of the PRA methodology is frequently traced to NUREG-75/014, "Reactor Safety Study" commonly known as WASH-1400 (Ref. 3.10). The most significant result of this work was that it provided a pattern for using PRAs at nuclear power plants, introduced the fault-tree concept to a large audience, and developed a reliability database. Experience with applications of this method showed that risk contributors can come from many areas associated with facility operation, not just catastrophic events, as previously thought. This study also discussed the importance of human performance, test and maintenance, and the concept of common-mode interactions.

With respect to the use of a PRA by NMSS/FSME, staff can define the following general objectives:

- Identify initiating events and event sequences that may contribute to risk.
- Provide realistic quantitative measures for the likelihood of the risk contributors.
- Provide a realistic evaluation of the potential consequences associated with hypothetical accident sequences.

- Provide a reasonable risk-informed framework for making regulatory decisions regarding facility design, operation, and siting.

One outcome of a PRA is a list of plant or facility responses to initiating events, and the sequences of events that can be expected. Through analysis of the significance of each identified risk contributor, it is possible to identify the high-risk sequences and then implement actions to minimize or mitigate them. These evaluations may include estimates of latent cancers, immediate fatalities, facility or plant damage, or other consequence measures.

To accomplish these objectives, a PRA relies on several important steps. One critical step is the collaboration of experts from different disciplines. This group may characterize the normal and off-normal modes for the facility; develop and codify scenarios for the off-normal events; gather reliability data; examine the transport of effluents throughout the facility and offsite in the event of an off-normal event; and provide an understanding of other health, environmental, or economic impacts.

A PRA incorporates a logic model that identifies events that can lead to failures. The logic model incorporates two types of logic trees, the event-tree and the fault-tree. Fault-tree analysis is a deductive procedure for determining failures and human errors that could result in the occurrence of specified undesired events (also referred to as top events). The main purpose of the fault-tree, through deductive logic, is to identify the different failure pathways of the top event. Statistical methods are used to estimate the failure probabilities and unavailabilities of the basic events identified in the fault tree. Boolean algebra is used to estimate the failure probability of the top event. These calculations involve quantitative reliability and maintenance information, such as failure probability, failure rate, and repair rate. The event-tree analysis, by comparison, is inductive by nature. This analysis moves forward in time to delineate events generally through two-level logic trees: yes/no and fail/success. Overall descriptions of the methodologies and tools to perform a PRA are provided in NUREG/CR-2300, “PRA Procedures Guide - A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants” (Ref. 3.11) and NUREG/CR-2815, “Probabilistic Safety Analysis Procedures Guide” (Ref. 3.12). These sources, while useful, are dated. Much work has been accomplished in continuing development of PRA standards. 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.” One of the most critical parts of such an analysis is reliability data for various systems and components. Depending on the particular facility or process being modeled, data sources may include published data or actual facility data. Commercially available software is also available to assist with fault-tree and event-tree setup and analysis, as well as reliability and maintenance analyses.

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” (Ref. 3.13) provides examples of the results. Software models for the evaluation of human performance are also available. Staff must also understand external events (such as fires, floods, hurricanes, and seismic events) when quantifying risk for a given facility. To model these events, the likelihood and severity of each event, and the possible impact on the plant, must be evaluated. This includes an assessment of the impact of the external event on emergency planning.

Summary of PRA Method

A PRA analysis allows for a holistic and quantitative assessment of a given facility, process, or piece of equipment. Historical analysis has demonstrated the usefulness of the technique in modeling chemical plant accidents, the effect of accidents at these facilities on onsite/offsite risks and consequences, including latent cancers, and the financial implications of such events. However, past PRAs have shown that, depending on the intended use, modeling and evaluation techniques, quality of reliability data, assessment of the impact of human failure, external events, or consequence analysis may need to be further developed. Over the last 30 years, PRAs were mostly performed for light water reactors. The steps performed as part of the PRAs vary depending on the specific applications involved.

3.5.2 Integrated Safety Analysis (ISA)

Consistent with 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” and as defined in NUREG-CR1513, “Integrated Safety Analysis Guidance Document” (Ref. 3.6), an ISA is a systematic examination of a facility's processes, equipment, structures, and personnel activities, to ensure that all relevant hazards that may result in unacceptable consequences have been evaluated and appropriate protective measures implemented. The chemical industry also refers to ISA as a Process Hazard Analysis.

The regulatory basis for performing an ISA is contained in 10 CFR Part 70, which includes a requirement for certain licensees and applicants to conduct an ISA. The ISA is expected to form the basis of a safety program that requires adequate controls and systems to ensure safe facility operation. When applied to nuclear fuel cycle facilities, ISA techniques must address all applicable hazards and their potential for causing criticality incidents and radiological and chemical releases.

ISAs provide:

- A description of the structures, equipment, and process activities at the facility.
- An identification and systematic analysis of hazards at the facility.
- A comprehensive identification of potential accident or event sequences that would result in unacceptable consequences, and the expected likelihood of those sequences.
- An identification and description of controls that are relied upon to limit or prevent accidents and mitigate the consequences.
- An identification of measures taken to ensure the availability and reliability of the identified safety systems.

For NMSS/FSME-regulated facilities, unacceptable consequences include those that result in radiological and chemical exposure to workers or the nearby population. Exposure could be the result of a radioactive release, criticality incident, explosion, or other unplanned event.

ISA techniques use either an inductive or deductive analysis approach. The inductive analysis is a bottom-up approach that identifies possible accident sequences by examining deviations from normal operating conditions. The deductive, or top-down approach, is better suited for identifying the combinations of equipment failures and human errors that can result in an accident. The deductive approach identifies a top event that is usually a severe consequence and explains the various ways this event can occur. By determining root causes, the deductive approach provides assurance that common-mode failures are understood and addressed. One effective approach for implementing an ISA program is to combine both approaches. Staff can first use the inductive approach to identify the broad range of potential accidents and then turn to the deductive approach analyze a potential accident in detail.

Staff can use a number of ISA hazard evaluation methods:

- Safety review
- Checklist analysis
- Relative event ranking;
- Preliminary hazard analysis
- What-if analysis
- What-if/checklist analysis
- HAZOP
- Failure Modes and Effects Analysis (FMEA)
- Fault-tree analysis
- Event-tree analysis
- Cause-consequence analysis
- Human reliability analysis

Compared to the previously described PRA and its quantitative results, the insights from an ISA are qualitative or semi-quantitative, depending on the hazard evaluation technique used. Some of these methods (e.g., HAZOP, FMEA, fault tree, and event tree) may be used to provide input to a quantitative risk assessment.

The choice of the particular method will depend on the reason for conducting an analysis, the results needed, the information available, the complexity of the process, the availability of experienced personnel, and the perceived risk of the process. Appendix A of NUREG-1513 , “Integrated Safety Analysis Guidance Document” provides detailed flow charts that guide the choice of a particular method. Regardless of the method chosen, a team that is knowledgeable and experienced is essential to ensure the success of the effort.

Before conducting the ISA, the scope of the analysis must be defined, including the consequences of concern. For NMSS/FSME, these include radiological events, criticality, and chemical consequences that can affect public and worker health and safety. High-consequence events are those that have an acute effect on workers and offsite populations. Intermediate consequences are similar, but have lower exposure levels. To ensure an acceptable level of risk, 10 CFR Part 70.61, “Performance requirements” requires controls to ensure that the occurrence of any credible high-consequence event is highly unlikely and that the occurrence of an intermediate-consequence event is also unlikely. The ISA should also include site characteristics, structures on site, equipment and processes, and operating personnel, as well as credible external events.

Detailed and accurate process information is essential. This is one of the main reasons that a knowledgeable and experienced team must be assembled. To identify hazards in a facility, information on the materials used at the facility should be available. Staff should identify all materials that pose radiological risks, including what conditions would be necessary to support a self-sustaining reaction. For chemicals, staff should collect information on toxicity, flammability, reactivity, and other pertinent properties that may affect safety. The analysis should account for any interactions between the various hazards.

The results of the ISA provide several types of risk information:

(1) A list of the potential accident sequences

(2) The consequences of each sequence

(3) Information showing compliance with the performance requirements, which include qualitative likelihood requirements; e.g., likely, highly unlikely, and unlikely

(4) A description of the controls designed to prevent or mitigate accidents ("items relied on for safety")

Documenting the ISA lends credibility to its results by making the basis scrutable and by demonstrating the robustness of the analysis. Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material,” of 10 CFR Part 70 specifies documentation requirements for ISAs, and guidance on this subject is provided in NUREG-1520, “Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility,” and NUREG-1513, “Integrated Safety Analysis Guidance Document.” In addition to the NRC staff guidance on ISAs, the Nuclear Energy Institue has also provided guidance on the contents of ISA Summaries to NMSS/FSME licensees (Ref. 3.14).

Summary of ISA

The ISA is a form of analysis required by the NRC of specified licensees to support their overall safety program and to provide a documented safety basis. It is proving suitable for that purpose. A variety of analysis techniques can be used in an ISA. Different techniques may be used for different processes, to attain the appropriate regulatory results. These techniques include FMEA, HAZOP, fault trees, and others. These same techniques may be useful for general risk-informed decisionmaking, to address regulatory activities other than compliance with the ISA requirements. In fact, these techniques are widely used in industries other than nuclear industry. Guidance on the appropriate use of these techniques is found in NUREG-1513, “Integrated Safety Analysis Guidance Document.”.

3.5.3 Performance Assessment (PA)

As discussed in Attachment 2 to SECY-99-100, a PA is the risk assessment method of choice for Group 1 facilities. These types of facilities conduct HLW and LLW disposal, decommissioning (residual contamination), and mill tailings reclamation. For these types of facilities, the main concern is the potential exposure of receptors to radionuclides that are released by natural transport processes through various media, such as rocks, soils, and water. The main threat is environmental damage from long-term leaching of contaminants. The typical components comprising a PA are shown in Figure 3.2 (Ref. 3.15).

A PA is a systematic safety analysis that assesses what can happen, how likely it is, what the potential impacts are, and how these impacts compare to the regulations. For NMSS/FSME waste management facilities, the essential elements of a PA include:

- Description of the site
- Analysis of the events that would affect long-term facility performance
- Analysis of the movement of radionuclides from the place of storage to the environment (pathway analysis)
- Estimates of resultant doses to workers and the general public
- Evaluation of the existing uncertainties

The PA is a quantitative assessment method tailored to meet the risk assessment needs of an individual waste facility. For a simple disposal question, a bounding type of analysis may be appropriate, whereas for more complex facilities, a probabilistic analysis is called for. The PA is designed to be an iterative process. Initial screening calculations can provide insights on site performance. The initial screening process should also provide information on issues and data needs that should be evaluated during site characterization. As additional data and information become available, the modeling assumptions and input data can be re-evaluated and revised accordingly. To provide a robust result, staff must include uncertainty and sensitivity analyses. The most common sources of uncertainty in PAs are conceptual and process models, scenarios, data, parameters, and other coefficients. The purpose of a sensitivity analysis is to identify important parameters by determining the relative effect of each variable on the result.

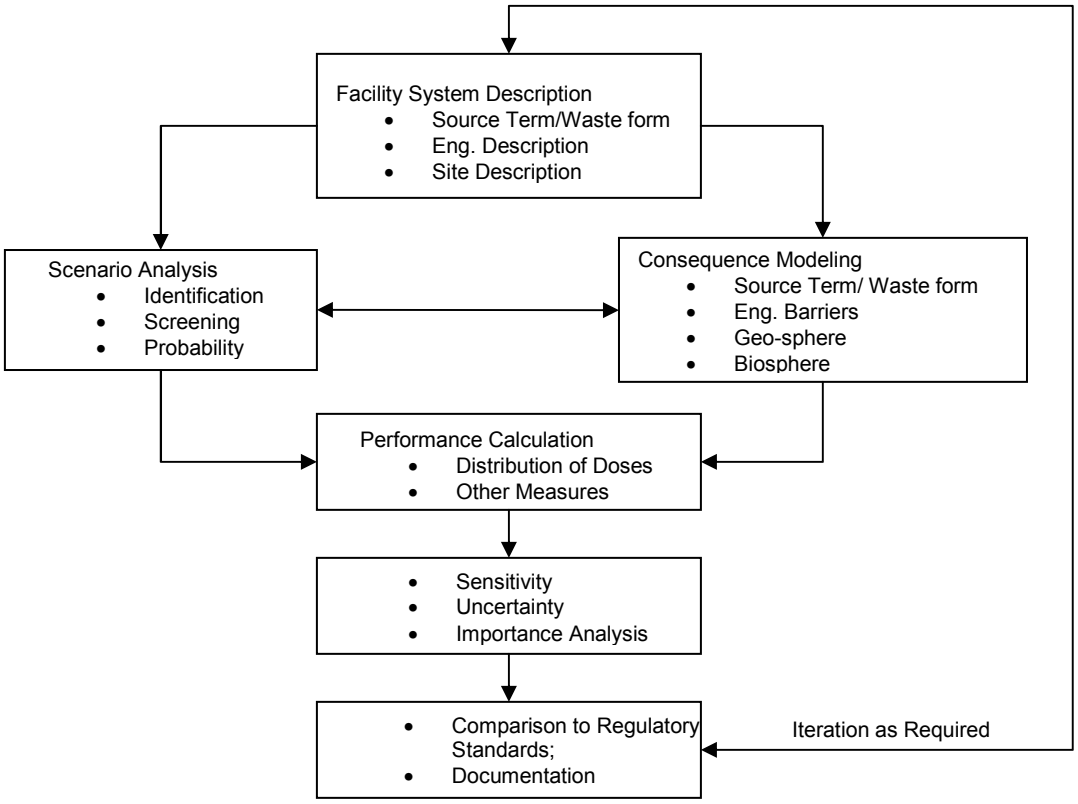

Figure 3.2 Components of a total system PA

As with all risk assessment models, documentation of the results and the assumptions used is critical. This requires information detailing the qualitative and quantitative data used, the conceptual models employed, the mathematical models used to represent the conceptual models, the computer codes used, sensitivity analyses, and a complete interpretation of the results.

With regard to NMSS/FSME regulation, a PA has several main uses. It can provide insights for rulemaking or the development of regulatory guidance. It allows for the review and understanding of licensee-submitted documentation, demonstrating compliance with regulations or providing justifications for requesting exemptions. A PA can also support the efficient expenditure of resources (money and personnel) and the identification of needed research.

Summary of PA

The quantitative aspects of the PA technique mirror the PRA methodology. It can be performed in an iterative fashion, incorporating new data and site characteristics as they become available. It identifies important issues and data needs that must be incorporated into the investigation and characterization of a waste disposal site. To provide defensible results, uncertainty and sensitivity analyses must be part of the PA process. Commonly cited sources of uncertainty focus on the model, process, and data uncertainties. Sensitivity studies identify the important parameters by determining the relative effect of each variable on the total system. For a PA to be successful, staff must be confident that the models used are performing as designed and are

capable of capturing all relevant features and processes of the disposal system being modeled (Ref. 3.16). Gauging this through formal validation exercises is often not practical because of the time required.

Chronic doses and their implied health effects are assessed for a period of time into the future. It is virtually impossible to predict, with any degree of certainty, beyond several decades in the future. Staff may need to evaluate probabilistically the likelihood of a resident farmer scenario, a building-occupancy scenario, and other potential scenarios, as well as the nature of the critical group. The authors recognize that there are great uncertainties in this area, and these uncertainties could be expressed in an analysis. Model and parameter uncertainties for the dose assessments could also be reflected in the quantitative assessment of risk. Staff would also have to assess the probabilities for the occurrence of natural events that may disrupt a site over a long time period of time. Staff would calculate the consequences of an event in terms of transport of radionuclides to the environment and their potential health effects. Staff would also assess human intrusions to the site.

It is difficult for the staff to assess the long-term human and environmental condition of the site. Current stylized scenarios may be unduly conservative. The IAEA sponsored the BIOMASS Program (Ref. 3.17), one attempt to assess the long-term radiological impact on a site. One objective of this program was to develop the concept of "reference biospheres," to assess the long-term safety of repositories for radioactive waste. This would also have implications for the residual radiological impact of a site that has been decommissioned. The basic idea was to develop a subset of sample biospheres that can provide a useful point of reference as broadly applicable indicators of potential radiological releases. Difficulties arose with the "reference biosphere," when researchers considered a wide variety of climates and topographies. The researchers produced a process to promote transparency and traceability on the biosphere modeling effort. Application guidance for this method is provided in NUREG-1757, "Consolidated NMSS Decommissioning Guidance--Characterization, Survey, and Determination of Radiologic Criteria."

3.5.4 Barrier/Hazard Analysis (BHA)

As discussed in SECY-99-100, staff can analyze the risks associated with the use of either sealed or unsealed byproduct material for a wide variety of industrial and medical applications (identified as Group 4) by using several different risk assessment techniques. In the past decade, PRA was used to study the risk associated with specific medical procedures. Though the result was positive, it was costly and had some specific limitations. Although analysts identified human error as the principal accident initiator, they found that the fault-tree/event-tree methodology was an inadequate tool for analyzing such accidents. SECY-99-062 (Ref. 3.18) discusses NRC progress in risk assessment methods for this group. Staff has identified the BHA method as being most useful for this group.

NUREG/CR-6642., “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,” (Ref. 3.19) discusses this assessment technique and ranks byproduct material systems according to risk (similar to the various programs identified in Inspection Manual Chapter 2800) (Ref. 3.20). This report evaluated the various scenarios that may result in worker or public dose, and their probability of occurrence. This ranking was based on

quantitative measures of several risk measures addressing individual worker dose and normal use versus accident scenarios.

Similar to all risk assessment methods, the first step is a comprehensive understanding of the nature and uses of byproduct materials throughout the life cycle of the radioactive material, from receipt by the user to final disposal. These topics include:

- System scope, including specific byproduct material used
- Basic process, equipment, and devices involved
- Review of current byproduct regulations
- Identification of hazards
- Tasks associated with the handling and use of byproduct material
- Personnel exposures
- Radioactive barriers and controls during normal and off-normal conditions
- Potential accidents and occurrences that could result in inadvertent exposure

The information required to complete this data gathering can be obtained from a variety of NRC, industry, and independent sources. NRC databases of value include the Licensing Tracking System (LTS); Sealed Source and Device Registry (Ref. 3.21); and the Nuclear Material Events Database (Ref. 3.22). The LTS is an internal NRC database that contains information regarding general and specific licenses issued; it can be accessed only by NRC staff. Other databases are maintained by Agreement States (Ref. 3.23), and can also provide occupational exposures and event descriptions.

For each system, analysts have identified he barriers and controls that could prevent or mitigate radiological hazards from byproduct material Barriers or controls are anything that limit or reduce the "likelihood," "magnitude," or "radiation exposure" (occupational or public), under both normal and off-normal conditions. Barriers and controls may be either physical barriers or administrative controls. Then the analysts performed a preliminary hazard analysis. This approach is very similar to the HAZOP technique. The analysts used results of this in the risk assessment to develop accident scenarios.

In performing the radiation-risk assessment, several exposure pathways are explicitly analyzed. These include external exposure from the source, inhalation of radioactive material released to the air, ingestion of radioactive material, and external exposure resulting from submersion in an airborne radioactive material cloud. As part of the analysis, staff should also considered the dose attributed to ground contamination from airborne transport and deposition to an offsite location. Appendix A of NUREG/CR-6642, “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,” provides equations to evaluate the consequences of each of these pathways.

The next step in the process is for the analysts to develop the potential scenarios and end states that could lead to radiation exposure. The analysts developed a set of credible scenarios based on actual experiences. The analysts determined the estimated frequency of each scenario and used it to quantify the risk. Although the approach is to quantify the risk, valid data for all scenarios do not exist. For these instances, the analysts made a qualitative assessment of the likelihood. Historical data, where available, offers the best source of risk quantification.

The Byproduct Material System Risk Assessment Database (Ref. 3.24) is a software program that performs the calculation of byproduct material risk, given specific normal and off-normal conditions. A description of this method is provided in NUREG/CR-6642.

Summary of the Barrier/Hazard Analysis Method

The BHA method is a relatively straightforward risk assessment method that staff can be apply to a wide variety of types and uses of byproduct material. The overall risk is provided in exposure (mrem) per event. It is a quantitative method, and like all analytical methods, is limited by the robustness of the assumptions underlying the modeling of off-normal events and accidents and the variability of the data contained in the various databases. Analysts can use Its results to assess the adequacy of the applicable regulatory requirements. For example, with these applications, one of the most commonly invoked barriers is public access control and source control.

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4 RISK-INFORMED DECISIONMAKING METHODS

4.1 Introduction

4.1.1 Decisionmaking Methods in the Overall Process

Figure 1.1 illustrates the overall RIDM process for NMSS/FSME-regulated activities and facilities. Figure 4.1 is an expanded version of Figure 1.1. It involves four basic steps, of which the final one is to apply structured algorithms. The decision-maker can use the structured algorithms to identify which alternatives appear preferable, based on risk insights and other considerations. This chapter suggests two such structured decision algorithms that will cover most, though not all, regulatory decision situations.

Like Figure 1.1, the starting point in Figure 4.1 is the identification of the regulatory issue or question. After the particular issue is identified, the next step is to apply the screening considerations. Staff should apply screening consideration number 4 (Exhibit 2.1) to assess if there are judicial, statutory, policy, or similar considerations that would preclude the implementation of a risk-informed decision process. After applying screening consideration number 4, staff can consider the content of the issue to identify whether risk information is needed. For example, if the issue is purely administrative and does not affect safety, it is screened out.

If the issue is not screened out, then staff should gather information to address the risk-related aspects of the issue or action alternatives. Staff can then apply screening considerations 2 and 3 to assess the amount and quality of available quantitative risk information and, if it is not available, whether the cost of obtaining it is reasonable and commensurate with the issue under consideration. If it is not, then a qualitative risk assessment is performed, or adapted, to assess the change in risk qualitatively, as shown in Figure 4.1. If adequate quantitative risk information is available, staff can perform or adapt a quantitative risk assessment. In performing or adapting the risk assessment, it is important to ensure that the scope and depth of the analysis are appropriate to the issue; the risk metrics relevant to the issue, and their associated uncertainty, are reasonably well-characterized; and the recipients of the risk are identified. If applicable, staff can then apply the decision logic for various types of regulatory actions (Ref. 4.2), as shown in Figure 4.1.

4.1.2 Decision Methods and Algorithms

This document describes specific decision algorithms in Section 4.2. The first two algorithms address a very general situation where changes are proposed to existing requirements. To be applicable to the wide variety of situations and regulated activities in NMSS/FSME, these two algorithms address a full list of attributes that may affect the decision. The first algorithm focuses on exemptions or changes to existing license requirements that might result in significant impacts to cost, risk, security, or the environment. The second algorithm is applicable to proposed new regulatory requirements, especially those proposed for the purposes of reducing risk. This algorithm is closely related to the type of regulatory analysis (Ref. 4.1) applied to justify backfit. However, staff can apply it to any proposed requirement that might have significant impacts. Both of these first two algorithms apply criteria that consider risk to individual workers and members of the public. If the proposed regulatory change(s) meet these risk criteria, further criteria are applied in accordance with regulatory analysis guidance (Refs. 1.2 and 1.3). If all these criteria are satisfied, staff can perform a quantitative value-impact analysis. A value-impact analysis evaluates the effect of each of the proposed changes on costs, public health, security, and the environment. These impacts are considered jointly (summed if quantitative), to judge which of the alternatives has the highest net positive impact.

The information in this chapter is supplemented with two Appendices. Appendix B provides an overview of value-impact analysis and also includes examples of generic tables that can be used by staff to perform simple value-impact assessments. Appendix E provides a brief discussion of available information and reference sources for risk information in the materials and waste arenas.

4.1.3 Attributes Considered in RIDM

A risk-informed approach, as defined by NRC, considers both risk insights and other information. In fact, there are a number of different risk criteria to apply, and a large number of other attributes that need to be considered in making regulatory changes. Some of these will be listed here for information, but detailed guidance and a more extensive list of these attributes are found in NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook.” The main purpose of this chapter is to provide risk criteria for accident risks applicable to nonreactor accidents. For reactors, risk criteria are found in NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” applicable to decision situation 2, new requirements (backfit), or in Regulatory Guide (RG) 1.174, for decision situation 1, exemptions and changes. No analogous risk criteria exist for accident risks that are generically applicable to these same decision situations in the nuclear material and waste arenas. Risk insights addressing routine or chronic doses for materials and waste can generally be obtained from existing guidance based on 10 CFR Part 20, “Standards for Protection Against Radiation” annual dose limits and other requirements.

Staff developed draft quantitative risk guidelines to address the lack of generic guidance on the risk of accidents to individuals. Staff needed these guidelines to apply the structured decision algorithms. Chapter 5 describes these risk guidelines and the basis for them. Section 4.2 describes their use. The draft risk guidelines represent an accident-risk reference level that can be regarded as a negligible additional risk, compared to the risk faced by workers or the public from operations. If the estimated risk is greater than the risk guidelines, the decision-maker

needs to decide if additional analysis (e.g., a value-impact analysis) is necessary to determine whether a further reduction in accident risk is needed. These guidelines are not regulatory requirements, nor do they exempt any licensee from compliance with requirements.

Staff should evaluate each proposal for a change to a licensing basis in a similar fashion, to ensure that all attributes for which the agency is responsible are addressed. This of course includes public health, safety, and environmental protection. The following discusses some of the attributes that are assessed when applying the methods in Section 4.2, together with regulatory analysis.

When considering a proposed change to a regulatory requirement, the decision to proceed or grant the change should be based on the evaluation of all relevant attributes. Following are some of the more important attributes:

(1) Staff should consider the effect of the proposed change on regulatory requirements other than the one being changed. Compliance must be maintained with all other requirements. One cannot just focus on the desired effect of the proposed change but must assess its overall effects as well.

(2) Staff should consider the effect of the proposed change on the defense in depth philosophy. Defense in depth guards against over-reliance on any one safety feature. For example, defense in depth may be provided by additional barriers, operating procedures, and limits, or by redundant and diverse equipment design. Staff must evaluate any changes that result in the elimination of a layer of protection and fully understand the consequences.

(3) Staff should consider the effect of the proposed change on safety margins. Quantitative risk models may not directly capture the effect of reduced margins. Staff should therefore be aware of the need to maintain margins, consider the possibility of reduced margins, and assess any impact.

(4) Staff should consider the effect of the proposed regulatory action on normal doses and accident risks to workers and the public.

(5) Staff should consider the effect of a change to the licensing basis, if approved. Changes that might result in increased risk to the public, but nevertheless are found to be acceptable in terms of this guidance, may benefit from a program to monitor risk-related performance in the area affected by the change.

The following offers a discussion of adequate protection and how risk, defense in depth, and safety margins are involved in this question. Regulatory analysis guidance (Ref. 1.3) indicates that when a regulatory action is proposed, it must be evaluated to assess whether adequate protection of public health and safety will be maintained and whether the action is consistent with the common defense and national security.

A licensed activity that complies fully with the applicable NRC rules and regulations is presumed to meet the “adequate protection” standard. The term adequate protection is introduced in the Atomic Energy Act (Ref. 4.2) and, more recently, in various regulations (e.g., in 10 CFR Part 50.109). The regulatory analysis guidelines NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (Ref. 4.1) define adequate protection as follows: “*The risk level associated with adequate protection is that level above which continued operation would not be allowed.”* and “The level of protection constituting ‘adequate protection’

is that level which must be assured without regard to cost. It is to be determined on a case-by-case basis. The determination should be based on plant- and site-specific considerations and the body of NRC's regulatory requirements."

The concept of adequate protection has also been discussed in RG 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," (Ref. 4.3). Although there is no single quantitative risk value associated with the notion of adequate protection, the risk level implied by the quantitative safety goals is more stringent (i.e., lower) than that implied by adequate protection.

Defense in depth is an element of NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs. Diverse and redundant barriers and safety systems serve to reduce the failure probability and increase the chance of success. The ACNW&M and the ACRS have jointly recommended to the Commission that risk-acceptance criteria be developed for all NMSS/FSME-regulated activities, to achieve defense in depth by balancing compensatory measures (Ref. 4.5).

Defense in depth can be achieved by a variety of different measures such as passive containment systems (e.g., multiple barriers), active systems (e.g., ventilation systems), and administrative procedures. Redundancy and diversity can be used to manage uncertainties associated with system reliability. Hence, a minimal level of defense in depth may be necessary, despite very low quantitative risk estimates.

A safety margin is a measure of the conservatism that is employed in a design or process to assure a high degree of confidence that it will perform a needed function. It can be defined as the probability or level of confidence that a design or process will perform an intended function. Sufficient safety margins should be maintained under any proposed regulatory change that relies on a risk-informed decision framework. This is typically done by demonstrating that sufficient conservatism is preserved in the design parameters, such that reliability and effectiveness are reasonably ensured against the most demanding challenge. An alternative approach often used is to demonstrate adherence to the acceptable Codes and Standards. Similar considerations are applicable to NMSS/FSME facilities.

Defense in depth and safety margins are both concepts that are used to address the impact of uncertainty on safe design and performance. Effective use of defense in depth and safety margins increases the likelihood of success in response to challenges.

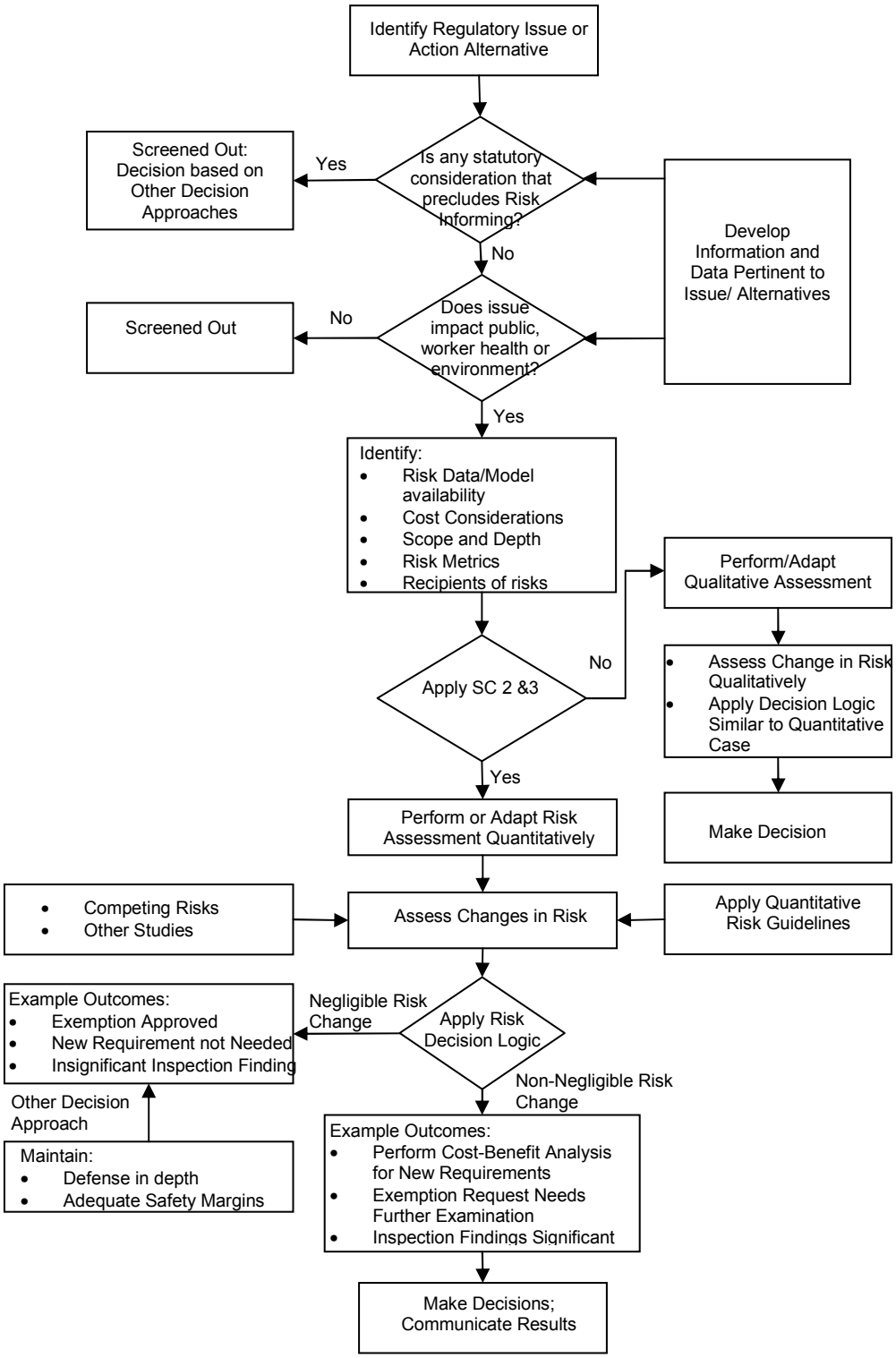

Figure 4.1 Risk Assessment Process

4.1.4 Risk Guidelines

Different types of public health and safety impacts may result from regulated nuclear material and waste activities. These impacts might include routine radiation exposures in the course of normal operations, residual chronic exposures from decommissioned or waste disposal sites, and accident risk. For routine and chronic exposures 10 CFR Part 20 provides regulatory limits and constraints that must be considered in the decisionmaking process. For accident risk, a few regulations covering certain specified activities provide qualitative and quantitative risk requirements. Since not all activities involving accident risk are covered by these few regulations, this document provides quantitative accident risk guidelines to inform decisions. These guidelines, as described in the subsequent chapter, were developed as reference levels of risk to individuals that are negligible relative to risks normally experienced. Section 4.2.2 of this chapter uses these guidelines to aid in screening out proposed new safety requirements that are unlikely to be justified because the level of risk is already negligible.

In using accident risk and expected routine radiation exposures to make a decision, competing risks, cost impacts, and other factors should be considered jointly. Risk-informed decisions are not made on the basis of comparison with risk guidelines alone. All factors, including requirements in the regulations, the philosophy of defense in depth, safety margins, risk to individuals, and regulatory analysis should inform appropriate decisions.

4.2 Decisionmaking Processes

The types of algorithms needed in the overall decisionmaking process depend to some extent on the particular issue involved. In the context of NMSS/FSME decisionmaking, the first decision algorithm (i.e., a value-impact analysis of a specific regulatory issue or action alternative) is broadly applicable. In fact, NUREG/BR-0184,“Regulatory Analysis Technical Evaluation Handbook” (Ref. 4.6), provides a number of examples of the use of value-impact analysis in nonreactor nuclear facilities.

In value-impact analysis, the costs of implementing the proposed action are compared with the benefits. The value-impact analysis identifies all the attributes (i.e., the risk metrics affecting public health and safety, occupational health and safety, and the environment/property) that are potentially affected by the issue or action, and estimates the change in their values after implementation of the proposed action. If the net present value is positive, then the action is deemed beneficial and passes the value-impact test. NUREG/BR-0058, the regulatory analysis guidelines document mentions that for nuclear power plants, regulators should use an 80 km distance from the plant site to estimate changes in public health and safety from radiation exposure and futhermore that “the appropriate distance for other types of licensed facilities should be determined on a case-by-case basis." The same document also recommends that “…health risks should be estimated for both routine operations and accidents." For NMSS/FSME-regulated facilities and activities, determination of the appropriate population at significant risk from implementing a proposed action is an important element in estimating the impact on public and worker health and safety. Risk assessments of the diverse facilities and activities have provided important information in this regard. Appendix B discusses the main attributes that need to be assessed in a value-impact analysis. This document also provides

generic tables to illustrate how the information would be assembled to document the analysis. The exact format for the tables would depend on the specific application.

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," addressed another decision algorithm in relation to reactor safety goal evaluation. The authors of NUREG/BR-0058 designed the safety-goal-evaluation algorithm to assess imposition of generic regulatory requirements (e.g., backfitting), and to determine whether an action meets the substantial added protection standard of 10 CFR Part 50.109(a)(3). The quantitative objectives of the reactor safety goals, to which this algorithm refers, are applicable only to accidents at NPPs. The authors based the safety-goal evaluation decision algorithm of NUREG/BR-0058 on fractional reductions in the CDF (and the conditional probability of early-containment failure, given core damage).

As accident risk guidelines do not officially exist for NMSS/FSME, there is currently no analog of the reactor safety goal decision algorithm in NUREG/BR-0058 for NMSS/FSME activities. However, the recently amended 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” and 10 CFR Part 76, “Certification of Gaseous Diffusion Plants” include one important element—requirements related to backfitting. In particular, consideration of the substantial increase in the protection standard, along lines very similar to those found in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.” If the NRC adopted risk guidelines for NMSS/FSME-regulated facilities and activities, an important application would be in testing the substantial added protection standard, as is done for power reactors in NUREG/BR-0058. However, the technical details of the procedure would be quite different, since there are no analogs to core damage frequency (CDF) and large early release frequency (LERF) in the activities, devices, and processes regulated by NMSS/FSME.

Figure 4.1 shows two possible outcomes, depending on the results of applying the risk decision logic. One outcome is for a result that shows a non-negligible risk change, and the other, a negligible risk change (while maintaining defense in depth and adequate safety margins). For the non-negligible risk changes, sample results may be used to perform a cost-benefit analysis, recommend further examination of the exemption request, or make a decision based on significant inspection findings. For those exemptions that staff find to represent a negligible risk change, specific outcomes may be the approval of the exemption, a finding that a new requirement is not needed, or a decision based on the absence of significant inspection findings. In general, burden reduction on the licensee would tend to increase risk, imposition of new requirements would tend to reduce risk, and decisions based on inspection findings would tend to maintain safety at existing levels.

The following sections present two possible algorithms for decisionmaking in each of the application areas discussed above. For exemptions and changes to the licensing basis of a facility that would tend to increase risk, very general guidance is taken from the example in RG 1.174. The procedure suggested here shows how *specific* requirements may be relaxed if the initial risk is already low and the incremental increases from a change are also small. The second algorithm relates to the potential introduction of new *generic* requirements. The general philosophy of the “Regulatory Analysis Guidelines,” NUREG/BR-0058, is followed and a "safety goal screening step" is introduced into the analysis process.

The decision algorithms presented below relate to six health metrics. The base values for these guidelines for negligible accident risk proposed for evaluation are:

(1) Public individual risk of acute fatality (QHG 1) is negligible if ≤ $5x10^{-7}$ /yr;

(2) Public individual risk of latent cancer fatality (QHG 2) is negligible if ≤ $2x10^{-6}$ /yr or 4 mrem/year;

(3) Public individual risk of serious injury (QHG 3) is negligible if ≤ $1x10^{-6}$ /yr;

(4) Worker individual risk of acute fatality (QHG 4) is negligible if ≤ $1x10^{-6}$ /yr;

(5) Worker individual risk of latent cancer fatality (QHG 5) is negligible if ≤ $1x10^{-5}$ /yr or 25 mrem/year; and

(6) Worker individual risk of serious injury (QHG 6) is negligible if ≤ $5x10^{-6}$ /yr.

In response to an Advisory Committee on Nuclear Waste and Materials (ACNW&M) recommendation, the latent cancer QHG values, which are in units of fatalities, can be converted into equivalent doses by using the ICRP conversion factors of $5x10^{-4}$ fatalities/rem for the public, and $4x10^{-4}$ fatalities/rem for workers.

In most specific applications thus far encountered in the materials and waste arenas, only one or two measures have been pertinent to the particular safety issue. This tends to keep the problem manageable in terms of decisionmaking. However, for rare situations in which several of the six health measures are important to an issue, there are decision-theoretical approaches, such as a multi-attribute theory, that can aid staff when considering several decision variables simultaneously (Ref. 4.7).

Accident risk is generally dealt with qualitatively in the rules and regulations. The quantitative risk guidelines are only guidance and are not requirements. The metric suggested here is the annual frequency of an undesirable health effect from an accident[1]. The risk guideline (the lower line in Figure 4.2) provides a benchmark for assessing what level of risk is regarded as negligible and is a universal concept, independent of any particular application. The upper line, in Figure 4.2 corresponds to the concept of reasonable assurance of adequate protection. Commission guidance on this issue has refrained from ascribing a numerical value to the concept of adequate protection that is evaluated on a case-by-case basis. For purposes of decisionmaking, however, as discussed in Section 4.2.1, trial values of a frequency or probability that would correspond to the upper line in Figure 4.2 can be used on an interim basis.

As pointed out in Chapter 1, staff must consider both routine and accident risks in risk-informed decisions. Rules and regulations deal with routine risk or exposure quantitatively. The metric for assessing routine risk is annual exposure and 10 CFR Part 20 prescribes what is legally unacceptable (i.e., exceeding the public and worker annual limits). However, Part 20 also makes ALARA (as low as is reasonably achievable) (i.e., to reduce exposures to as low as reasonably achievable) a legal requirement in planning radiation-related activities. However, ALARA is not a one-size-fits-all concept, since what is possible (i.e., achievable and

[1] Note that there are several approaches under consideration for possible accident-risk guidelines for NMSS/FSME regulatory applications. For illustration purposes, the metric of annual frequency of an undesirable health effect is used in the suggested decision algorithms.

reasonable) will vary, depending on the particular application, technology involved, and costs and benefits of implementation. A diagram similar to Figure 4.2, focused on routine risk, can help in the decisionmaking process. In the diagram that applies to routine risk, the upper line separating the unacceptable from the tolerable would be the appropriate regulatory limit from 10 CFR Part 20 (100 mrem/yr for the public and 5 rem/yr for workers). If a specific limit applies to a specific source or practice (e.g., 10 CFR Part 63), that specific limit is to be used for that activity.

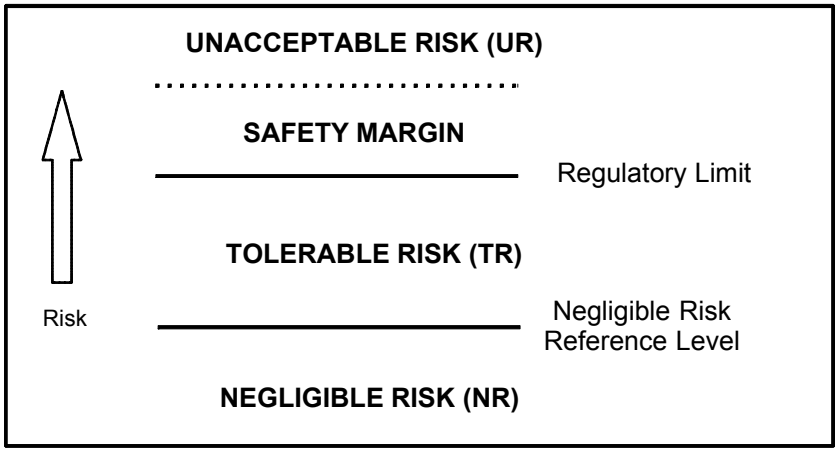

Figure 4.2 Three-region risk diagram

4.2.1 Exemptions and Changes to the Licensing Basis

RG 1.174 provides guidance to reactor licensees on using risk information to support licensee-initiated changes to the licensing basis of an NPP that require review and approval by NRC. RG 1.174 indicates that "...consideration of the Commission's Safety Goal Policy Statement is an important element in regulatory decisionmaking. Consequently, this regulatory guide provides acceptance guidelines consistent with this policy statement." RG 1.174 remarks, however, that in the context of integrated decisionmaking, the acceptance guidelines should not be interpreted as being overly prescriptive. They are approximate values that provide an indication of what is generally acceptable, rather than being strict numerical criteria.

The Reactor Safety Goals have two tiers: qualitative and quantitative. In addition, there are subsidiary objectives, below the quantitative goals, that are useful for more direct computation of risks. This third tier is not formally part of the Reactor Safety Goals. The risk acceptance guidelines recommended in RG 1.174 are based on estimating the changes to the subsidiary objectives, CDF and LERF, from the proposed change in the licensing basis. The licensee's plant-specific PRA is used to estimate the change in CDF and LERF and the needed sophistication of the analysis, including the scope of the PRA (i.e., whether it covers only full-power operation and internal events, or whether it extends to lower and shutdown operation and also to external events), is stated to depend on the contribution the PRA makes to integrated decisionmaking, and on the extent of the potential impact on risk of the proposed action or change. Numerical guidelines are recommended for ΔCDF and ΔLERF that indicate which changes will be considered broadly acceptable, which will be considered unacceptable, and which will require further technical review. These numerical guidelines are derived from, and

are based on, the values of CDF and LERF (1 $x10^{-4}$ and $1x10^{-5}$ per reactor-year, respectively) that are consistent with the reactor safety goal quantitative health objectives (QHOs).

One difference between light water reactors and NMSS/FSME applications is that currently there is no readily identifiable and universal analog of the Tier 3 reactor subsidiary objectives CDF and LERF for NMSS/FSME-regulated facilities and activities. NMSS/FSME-regulated facilities and activities vary widely with respect to technology, quantity of radioactive material involved, and operation. They range from large, stationary facilities, such as enrichment or fuel fabrication plants, to small sealed sources. Because of this variety, subsidiary objectives may not be warranted for each facility and activity. Regulators will not determine the need and identification of suitable Tier 3 subsidiary guidelines for this diverse set of activities until more experience is gained.

A different procedure from RG 1.174 for reactors has been developed here. The suggested procedure is to use the quantitative health guidelines (QHGs) directly in the risk-guideline decisionmaking algorithm. Unlike reactors, where the endpoints are often CDF and LERF, in many risk assessments of NMSS/FSME facilities, radiation doses to the affected population are frequently the endpoint of assessment. This is particularly true for industrial and medical applications, where the population potentially affected by an accident or during a routine operation is often located in the immediate vicinity of the source or device (see NUREG/CR-6642).

The three-region risk-acceptance diagram shown schematically in Figure 4.2 presents the suggested procedure. This diagram divides the risk space for any of the applicable risk metrics (public acute fatality, worker acute fatality, public latent cancer, etc.) into three regions: an unacceptable-risk region, a tolerable-risk region, and a negligible-risk region. The lower bound, shown in Figure 4.2, that separates the negligible-risk region from the tolerable risk region (TR) is the risk-guideline QHG value. The upper bound corresponds to the risk implication of the regulatory or safety limit that constitutes what is implied by "adequate protection" and separates the unacceptable-risk from the tolerable-risk region. The TR range is divided into two halves, an upper-TR (UTR) range and a lower-TR (LTR) range.

To see how the risk-acceptance diagram would apply in decisionmaking, consider the risk space pertinent to the worker prompt-fatality risk metric. The lower boundary separating LTR and NR corresponds to a frequency of 1 E-6/facility-yr (corresponding to the proposed worker prompt-fatality QHG 4). Staff can assume the upper boundary to have some higher value. One approach would be to have each region in Figure 4.2 separated by one order of magnitude. Thus, for the worker prompt fatality risk metric, the line separating LTR from NR corresponds to 1 E-6/ year, the line separating LTR from UTR corresponds to 1 E-5/ year, and the line separating UTR from UR corresponds to 1 E-4/year. (This is somewhat similar to the algorithm discussed in RG 1.174, where the corresponding adjacent regions for ΔCDF (and ΔLERF) differ by one order of magnitude.) The approach suggested here is just that: an approach for discussion. Staff should consider and evaluate other approaches as well, especially those that define the upper boundary separating the UR and TR regions. Just as the risk guidelines themselves were derived based on percentages of the corresponding background risks faced by the public or workers [see Chapter 5), the upper boundary could be based on higher percentages of the same background risks.

Consider another case, where the decision involves the worker latent-cancer fatality risk metric. In this case, one approach, for the boundary separating the UR and TR regions, is to assume that the upper limit for annual fatality risks from accidental exposures is the same as the annual dose limit from normal operation converted via the BEIR-V conversion factor to probability of fatality. Hence, the 5 rem annual dose limit for workers would translate into a 2E-3 annual probability of latent cancer for workers. If a decision involves the public latent cancer metric, the upper bound separating the UR from the TR region could be taken as the 10 CFR Part 20 limit of 100 mrem/yr (that translates into a 5E-5 /yr risk of latent cancer fatality using the BEIR-V conversion factor). The lower bound in this case would be the draft risk guideline QHG 2 of 2E-6 /yr. The line separating the UTR and LTR regions could then be assigned an intermediate value depending on the issue under consideration, value-impact analysis results, and other relevant factors. The suggested numerical values corresponding to the risk levels of the upper bound separating the region of UR from that of TR and separating the upper region of the tolerable risk from the lower region need considerable further input and deliberation from existing risk assessments, pilot studies, and stakeholders.

The risk-guideline decision algorithm process would then focus on the calculated mean values of the risk metrics before and after the action or issue under consideration is implemented. As in the case of reactors, the upper and lower bounds are ones considered broadly acceptable and not to be interpreted as strict numerical criteria; in other words, they are indicative of the risks that are considered acceptable.

There are six risk guidelines: three for risk to individual members of the public and three for risk to individual workers. For any given situation, the risk of each guideline lies in one of the four risk regions from unacceptable to negligible. The risk region to which the overall situation belongs is the highest one in which any of the six guidelines falls.

Table 4.1 Risk Acceptance Logic for Changes

		RISK REGION AFTER CHANGE			
BEFORE CHANGE		**Negligible**	**Lower Tolerable**	**Upper Tolerable**	**Unacceptable**
	Unacceptable	Consider other factors, value-impact? 4	Consider other factors, value-impact? 4	Consider other factors, value-impact? 4	Find a way to make risk tolerable 1
	Upper Tolerable	Consider other factors, value-impact? 4	Consider other factors, value-impact? 4	Change not normally considered 3	Change not implemented 2
	Lower Tolerable	Consider other factors, value-impact? 4	Consider other factors, do value-impact 5	Change not normally considered 3	Change not implemented 2
	Negligible	Consider other factors, value-impact? 4	Consider other factors, do value-impact 5	Change not normally considered 3	Change not implemented 2

Table 4.1 is a matrix showing all the possible situations regarding the risk regions before and after a proposed exemption or regulatory change. The risk region before the change is shown in the left column, and the risk region after the change is shown in the top row. Thus, each box in this matrix represents one of the 16 possibilities. These 16 possibilities are placed in five categories indicated by the number in each box. These five categories are discussed below.

(1) The risk after the change is still in the unacceptable region. This means both that the current situation is unacceptable and that the proposed change will not fix it. Therefore, a different regulatory change should be devised to lower the risk out of this region.

(2) In these cases, the proposed change causes the risk to increase from tolerable (or below) up into the unacceptable region. Such changes should not be implemented, but the current situation falls in the acceptable range.

(3) In the case of those changes labeled 3, the risk has increased into the UTR. This means that individual risk is being increased to high values. Normally, such changes should not be allowed unless outweighed by other considerations, or by exceptional net benefits as shown through value-impact analysis. In the one case where the risk starts and remains in the upper tolerable region, if there is actually a decrease in risk, this situation may be categorized as a 5.

(4) The boxes labeled 4 (gray) are those where the change has resulted in a decrease in the overall risk region, or has remained in the negligible region. This does not necessarily mean that all risk metrics have decreased, but only that the highest one is now in a lower-risk region. Other risk metrics may actually have increased. However, in practice, changes in these boxes may represent a decrease in all risk metrics. If it is also clear that the change will decrease costs, it is probably unnecessary to perform a quantitative value-impact analysis in order to draw the conclusion that the change should be implemented. This is what is meant by the phrase "value impact" in these boxes. Note also that, even when all risk metrics decrease, a change may be rejected based on other considerations, such as inadequate defense in depth. These "other considerations" are, in part, discussed in this Chapter, but also in guidance on regulatory analysis (Refs. 1.2 and 1.3).

(5) These category 5 situations are the typical ones where the change results in an increase in the risk region, but remains at a lower tolerable or negligible level. Such increases in individual risk may be tolerable but need to be justified. The justification may involve an improvement in some "other consideration" or a clear net benefit shown by the value-impact analysis.

In addition, other qualitative considerations, such as those considered in Appendix B, may also have a bearing on the decision. Regulatory efficiency, safeguards and security, and improvements in knowledge are some of these factors that are often difficult to quantify but are nevertheless considered in the decisionmaking process. Other important factors to consider in the RIDM process, and that are shown in Figure 4.1, are those that address uncertainty (e.g., defense in depth and safety margins). It is important to comply with requirements that address the latter issues, particularly when considering possible action alternatives and their risk impacts.

4.2.2 Consideration of New Requirements

NRC requires a regulatory analysis for backfit (see Glossary) or whenever new generic requirements, guidance, or staff positions would effect a change in the expenditure of resources by licensees. The "Regulatory Analysis Technical Evaluation Handbook" and "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" provide guidance to the regulatory analyst on the preparation of such an appropriate evaluation. The guidance provided here is intended as a supplement to the above guidance that provides risk criteria applicable to nuclear material and waste. The guidance here is for trial use.

When considering new regulatory requirements in a risk-informed manner, there are several steps in the process, as explained in Ref. 4.6:

(1) Define the problem or issue.

(2) Define a number of alternative regulatory actions that might resolve the problem.

(3) Screen these proposed alternatives based on a number of attributes to eliminate those that fail to meet established criteria, or are clearly inferior to other alternatives.

(4) For the remaining alternatives perform value-impact analysis to aid in selecting the one appears to be best.

The attributes to be considered in Step 3, Screening, are basically those discussed in Section 4.1.3 and in the regulatory analysis guidance. We will supplement them here with criteria based on risk to individuals. These attributes include regulatory requirements or policy that are to remain in effect, defense in depth, safety margins, the effect on routine doses to workers and public, effect on regulatory efficiency, safeguards and security, and the environment. For each of these attributes there may be constraints that either eliminate a possible alternative, or which require that some element be included. These constraints may be explicit if they are a regulation or policy statement, but for others such as defense in depth and safety margins, there is no explicit generic guidance. The discussion in Section 4.2.3.1 implies that for defense in depth there may be a minimum level that should be met. As indicated in this section, the minimum level is not the same for all situations, but varies depending on a number of factors. Proposed alternative requirements not having this minimum level would be screened out. A similar logic applies for screening out alternatives based on insufficient safety margins.

One idea that is fundamental to regulatory analysis for backfit or new requirements is that the new requirement be justified. That is, there must be legitimate reasons for the requirement and its net impact on society, considering all impacts, should be positive. There are several different criteria that can justify a requirement. Some of these are listed in the exceptions in the backfit rules themselves. Another is what Reference 4.6 calls regulatory efficiency. In order to function, a regulatory agency must have sufficient information to make findings required by statute. Thus new requirements that request certain information or analysis in order to make such findings may require no further justification.

For reactors, the Regulatory Analysis Technical Evaluation Handbook states that the process of screening proposed new requirements includes a “safety goal evaluation.” This safety goal evaluation is described in Ref. 4.1. The guidelines in this reference indicate that one should not proceed with a regulatory analysis if the reduction risk is small when benchmarked against the subsidiary objectives for the risk guidelines. The rationale is that, if a new requirement is to be justified on the basis of its risk-reduction benefit, yet that reduction is very small, then it is not a substantial benefit. The proposed new requirement would also be unlikely to be cost beneficial, since the cost impact of most requirements on reactors is substantial. Non-reactor nuclear activities lack a single risk metric, such as large early release frequency (LERF), that can be used for such screening. Instead there are six risk metrics, with Quantitative Health Guidelines listed, each of which must be considered in the context of the three risk regions shown in Figure 4.2. Based on these concepts, a tentative decision algorithm, analogous to the reactor safety goal screening step for reactors, as described in NUREG/BR-0058, is provided in Table 4.2 below.

For proposed regulatory actions whose primary justification is to reduce risk from its present value, the reductions in individual risk should be estimated for each of the six risk metrics used in the Quantitative Risk Guidelines (QHG). That is, the six risk values are measured in the units of the pertinent QHG: worker - public; acute fatality - latent fatality - injury. Table 4.2 provides the necessary decision algorithm for considering the magnitude of the ***change in risk*** to be produced by the proposed regulatory action. Note that the absolute level of the six risk metrics should also be considered. When the purpose of the regulatory action is to reduce one of these six metrics, yet its absolute value is already below the negligible level of individual risk expressed by the QHG, then further reduction would not normally be warranted. Note also that the proposed action may have purposes other than reduction of these six accident risk metrics

which would justify proceeding with the remainder of the regulatory analysis. Examples would be actions to provide defense in depth or to provide needed information to the regulator. In such cases, the fact that the action also provides only a negligible risk reduction may not be the decisive consideration.

Table 4.2. Risk-Reduction Decision Logic for NMSS/FSME Facilities

Risk-Reduction of Proposed Regulatory Action	Staff Response
Δ Risk for any of the 6 risk metrics > QHG	Proceed with regulatory analysis
10% QHG < Δ Risk for any of the 6 risks metrics< QHG	Conduct appropriate staff management reviews of other factors to determine whether to proceed with a regulatory analysis.
Δ Risk for all 6 risks metrics < 10% QHG	Action is not recommended.

The final step in the evaluation of proposed alternative requirements is to perform a net value-impact analysis to aid in selecting the best alternative. If staff is considering the proposed new requirements in order to decrease risk, a value-impact analysis should be to evaluate the total collective risk of the affected facilities. This is the baseline risk. It includes risk to the offsite public and to workers, both routine exposures and accident risk. This risk is summed over all persons at risk, then converted to dollars at $2000/person-rem or $3 million per fatality. If the proposed new requirements completely eliminated all risk, this dollar value would be the benefit of the requirement in averting risk. Thus this dollar value is the maximum possible risk reduction benefit. Any of the proposed alternative sets of requirements that exceed this value is thus screened out as not justified; unless justified on other grounds discussed above.

For alternatives which make it through the screening process, a quantitative value-impact analysis for each alternative is needed. In this analysis, staff estimates all effects on costs and risks of each proposed alternative set of requirements. Staff then adds these cost and risk changes (relative to the baseline case) to obtain a measure of net benefit. The alternative with the highest net benefit is thus the preferred one, provided that this value is positive. Proposed alternatives whose net benefit is negative fail the justification test. This value impact analysis process is described in Appendix B.

4.2.3 Consideration of Risk-Related Issues in Implementing Above Algorithms

The RIDM process frequently occurs in the context of changing requirements that may have been in place for many years. This is particularly so in the context of reducing requirements that may have been routinely imposed in the past; their removal may encounter significant opposition from staff who championed them earlier. The issues that have to be carefully considered are those that involve safety margins and defense in depth and those that have to be applied generically, rather than on a facility-specific basis. In the former case, the issue is to determine the correct level of safety margin (i.e., determine the right amount of conservatism in the design or process, by maintaining the desired level of safety while avoiding excessive defense in depth). In the case of generic versus facility-specific issues, how reasonable is it to extend the results of risk studies that may have been performed only for a specific design or a specific facility to other, perhaps similar, designs at other locations? In short, what are the implications of generalizing the results of studies on specific facilities to a generic class of facilities?

Although there are no simple or straightforward answers to these questions that arise frequently in the RIDM process, staff may find it useful to consider a few relevant factors.

4.2.3.1 Defense in Depth and Safety Margins

In the case of safety margins, staff should consider whether, for example, more than one level of safety margin is being applied in a particular case so that the end result is layer upon layer of conservatism. As an example, consider an accidental leak of radioactive material through one or more barriers, its subsequent transport under atmospheric conditions to the site boundary, and the possible dose given to a receptor. If staff uses the most conservative bounding value of the accident stress to calculate the probability of barrier rupture and the most conservative weather condition to estimate the site boundary dose, this approach can lead to an excessive safety margin. It is not a risk-informed approach. It is preferable to do each calculation on a best-estimate basis and to then apply conservatism, as warranted, to the overall result. That said, consideration of uncertainty is important. If reasonably complete uncertainty calculations are available, the degree of needed conservatism can be estimated and additional conservatism is not needed. For example, an hourly set of annual weather data is used in probabilistic-consequence-assessment codes to estimate the uncertainty in dose, given a release. The less such information regarding uncertainty is available, the more the staff may need to adopt conservative approaches.

In the decision algorithms, risk information needs to be used in a fashion consistent with the Commission's overall defense in depth philosophy. This philosophy helps ensure that key safety functions do not depend on a single element of design or operation and that uncertainties are taken into account. The extent of defense in depth can vary depending on the nature of the risk and/or uncertainty. The application of the defense in depth philosophy is, in fact, aided by the use of a risk-informed decision process, in that the risk-informed process provided generally employs quantitative guidelines that can be used in deciding on the need for, extent, nature, and effectiveness of defense in depth measures. In general, the relation between defense in depth and a risk-informed process can be summarized as follows:

- For low-risk/consequence activities, where uncertainties are also low, defense in depth measures can be reduced.
- For medium-risk/consequence activities, defense in depth measures should be considered to ensure that the levels of safety can be met with a specified level of confidence. The defense in depth measures considered should include:
  - Ensuring key safety functions do not depend on a single element of design or operation;
  - Using redundancy, diversity, and independence to improve reliability and/or avoid common mode failure, when necessary, to ensure safety is maintained;
  - Providing safety margins to address uncertainties in modeling or equipment performance;
  - Conducting regulated activities at locations that facilitate protection of public and worker safety; and
  - Providing time for recovery operations.
- For high-risk/consequence activities, defense in depth measures similar to the above should be considered, as well as:
  - Ensuring the design and operation have both accident prevention and mitigation measures; and
  - Ensuring the design includes at least two independent barriers to the uncontrolled release of radioactive material.

Accordingly, in making risk-informed decisions, one needs to consider whether defense in depth measures are needed (or could be relaxed). If the defense in depth measures are needed, consider the degree to which they are needed, based on the application of this process. In all cases, staff should monitor regulated activities to ensure that key assumptions used in the risk analysis remain valid and adjustments are made to reflect operating experience where necessary. In general, low-risk/consequences mean doses are in the range of 10 CFR Part 20 limits. High-risk/consequences mean doses can be large enough to cause one or more early fatalities; medium-risk/consequences correspond to the range between low and high.

Please note that risk information can only provide defense in depth insights on the known uncertainties. However, risk information cannot provide defense in depth insights on the unknowns.

In Appendices N and O, this document provides additional guidance on the considerations related to defense in depth and safety margins.

4.2.3.2 Generic vs. Facility-Specific Issues

Regarding generic versus design- or facility-specific issues, one can take the example of the dry storage cask PRA that RES recently carried out for a specific design at a specific location (Ref. 4.8). Ask how valid and applicable its results are on a generic basis. In other words, can these results be applied generically? Two factors are involved. One is cask design and the applicability of the failure modes and effects and potential releases from a specific design to all designs. The other is site location and whether the results obtained from a specific site are broadly applicable everywhere.

In general, the key contributors to risk should be identified from a specific study. Then, in considering the applicability of that risk study more generically, the differences in the other system's design and operation should be assessed (at least qualitatively) with regard to the key contributors.

4.2.3.3 Graded Approach

In overall application of the RIDM process, it is useful to emphasize the benefits of a graded approach. In general, if the risks are very low, both in terms of frequency and consequence, it is not very important to refine the calculations beyond a first-cut estimate. However, if the situation is the opposite, and the risks are high in terms of both frequency and consequence, then expenditure of additional resources is warranted. Risk guidelines, of course, offer valuable guidance in framing what risks can be considered "low." Value-impact analysis can offer valuable guidelines here, as it provides a measure of the relative importance of the change in risk, just as the risk guidelines do.

4.2.3.4 Reaching Consensus on a Recommendation

The technical staff involved with the analysis will summarize the results for each decision option. The principal analysts in each discipline (e.g., PRA, engineering, licensing, etc.) will participate in the integration process with other technical staff through a facilitated discussion.

Additional guidance on the considerations related to reaching consensus on a recommendation is provided in Appendix P.

4.3 References

4.1 U.S. Nuclear Regulatory Commission, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, July 2000.

4.2 "The Atomic Energy Act of 1954," August 30,1954 as amended in NUREG-0980, "Nuclear Regulatory Legislation."

4.3 U.S. Nuclear Regulatory Commission, Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," July 1998.

4.4 U.S. Nuclear Regulatory Commission, Letter from Messrs. Garrick and Powers to Chairman Meserve, "Use of Defense in Depth In Risk-Informing NMSS Activities," May 25, 2000.

4.5 U.S. Nuclear Regulatory Commission Letter from Messrs. Garrick and Powers to Chairman Meserve, "Implementing a Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," November 17, 1999.

4.6 U.S. Nuclear Regulatory Commission, "Regulatory Analysis Technical Evaluation Handbook," NUREG/BR-0184, January 1997.

4.7 Hammond, J.S., et al., *Smart Choices: A Practical Guide to Making Better Decisions*, Harvard University Press, Cambridge, MA, 1998.

4.8 U.S. Nuclear Regulatory Commission, “A Pilot Probabilistic Risk Assessment of a Dry Cask Storage System at a Nuclear Power Plant,” NUREG-1864, September 2006.

5 RISK GUIDELINES FOR USE IN NMSS/FSME

5.1 Introduction

This chapter provides the technical basis for the draft risk guidelines used in the RIDM algorithms, discussed in Chapter 4. Risk guidelines represent an accident risk reference level regarded as a negligible additional risk, compared to the normal risks faced by workers or the public. The regulatory activity is generally considered safe enough when estimated accident risks to individuals are less than these risk guidelines. However, there are other considerations involved in making regulatory decisions. In addition to accident risk, risk from routine exposures to individuals must also be considered. Additional regulatory measures may also be needed to address safety considerations other than accident risk. For example, defense in depth, safety margins, and other programmatic elements may not be adequately addressed, even when the estimated accident risk is negligible. Further regulatory action may also be warranted to address nonsafety factors, such as environmental protection, the Administrative Procedures Act (Part 1, Chapter 5, Sections 511-599), or other statutory requirements. Although attaining negligible risk levels does not absolutely preclude a need for further efforts to reduce risk, the value of further reduction in risk is negligible; hence, such efforts will have difficulty meeting cost-benefit criteria. Cost cannot, however, be a consideration if a particular measure is found to be necessary, to attain adequate protection of public health and safety, or to be in accord with the common defense and security.

The multiple attributes and considerations that bear on decisions include risk but also include many other things (i.e., decisions should be risk-informed, not risk-based). It is the goal of this guidance document to provide a structured framework that ties together existing guidance addressing all these considerations, as a convenience to the staff in making decisions that change the regulatory process. This chapter focuses on one of these considerations; i.e., guidelines as to what level of accident risk to individuals should be regarded as negligible. Chapter 4 discusses how these guidelines may be used in specific decisionmaking situations and refers the reader to existing guidance documents, addressing the other considerations mentioned above.

Risk guidelines represent an accident-risk reference level that can be regarded as a negligible additional risk, compared to the risk faced by workers or the public from normal operations. If the estimated accident risk to an individual is less than, or equal to, the risk guidelines, it generally indicates that the regulated activity is safe enough and the regulatory resources can be used to focus on higher-risk activities. NRC staff can apply risk guidelines to rulemaking, licensing, inspection, or enforcement actions.

Appendix G provides one example of the use of risk guidelines in NMSS/FSME.

5.2 Three-Tier Approach to Risk Guidelines

The reactor safety goals developed in the "Safety Goal Policy Statement for the Operation of Nuclear Power Plants" (Ref. 5.1) (SGPS) have a hierarchical structure composed of three tiers: a top, qualitative tier, followed by a quantitative tier which is, in turn, supported by subsidiary objectives. Qualitative goals (Tier I) are stated in a language that is readily understandable to the general public and express the high-level safety aspirations of the agency. Quantitative goals (Tier II) are expressed in terms of health objectives related to the risk of an undesirable health effect from the regulated activity. Subsidiary objectives (Tier III) are expressed in terms of risk parameters related to specific engineering features of the technology (e.g., engineered barriers), whose failure(s) could lead to an undesired health effect.

For NMSS/FSME-regulated facilities and activities, the proposed draft risk guidelines can be expressed in a similar three-tiered hierarchical structure composed of high-level qualitative guidelines followed by quantitative health risk guidelines. Subsidiary guidelines may or may not add to a RIDM approach to NMSS/FSME regulatory activities. Such determinations would not be made until more experience has accumulated on the use of the draft risk guidelines. Therefore, subsidiary guidelines are not discussed further in this chapter. Note that the term "guideline" has been chosen to underscore that the quantitative values are not limits or standards, but rather guidelines that provide an indication of what can be regarded as an insignificant level of risk to assist risk-informed decisionmaking. Further, it is important to distinguish these guidelines from the "goals" and "objectives" of the SGPS, which have their own particular history and motivation and subsequent implementation in risk-informed decisionmaking in the reactor program.

5.2.1 Qualitative Risk Guidelines

As shown from the case studies in nuclear material waste and disposal (Ref. 5.2), the workers are the population that bears a significant portion of the risk, and SECY-99-100 (Ref. 5.3) has indicated that the risk metrics and goals should address the safety of workers. In many NMSS/FSME-regulated applications, worker risk exceeds public risk, in some cases by several orders of magnitude. Thus, ignoring worker risk would be ignoring the major recipient of the risk.

Accordingly, the qualitative risk guidelines for nuclear material and waste activities proposed below address both the public and the worker and are expressed in terms of individual risks. The guideline is:

> ***Individual**: Nuclear material and waste activities should pose a negligible additional risk to the life and health of individual members of the public and to workers associated with these activities.*

5.2.2 Quantitative Health Guidelines (QHGs)- Base Approach

In the reactor SGPS, the Commission specified the risk measures in which the qualitative safety goals would be couched and then defined what "no significant additional risk" meant in quantitative terms. In so doing, the qualitative safety goals were transformed into QHOs. A similar approach has been followed in developing the NMSS/FSME QHGs for the public and the workers, as stated below.

The three QHGs for individual members of the public apply to the population at significant risk (i.e., people in the vicinity of NMSS/FSME-regulated facilities or activities). The QHGs indicate what level of accident risk posed by these facilities should be regarded as "negligible additional risk" to the public, compared to everyday risks to which the average member of the public in the United States is exposed. In other words, when comparing or evaluating the results of quantitative risk assessments in making risk-informed decisions, the quantitative risk guidelines are simply meant to indicate what numerical level of risk will be regarded as "negligible." The six QHGs proposed for RIDM are given below. The rationale used to develop the QHGs is discussed in Section 5.3.

***Individual Public Acute** (QHG 1): A risk to an individual member of the public of a prompt fatality, due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. public are generally exposed. This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG1 value is $5x10^{-7}$ /yr.*

***Individual Public Latent** (QHG 2): A risk to an individual member of the public of a latent cancer fatality due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one-tenth of one percent (0.1 percent) of the sum of latent cancer fatality risks resulting from other accidents to which members of the U.S. public are generally exposed. This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG2 value is $2x10^{-6}$ /yr or 4 mrem/yr.*

***Individual Public Injury** (QHG 3): A risk to an individual member of the public of severe injury, due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one-tenth of one percent (0.1 percent) of the sum of severe injury risks resulting from other accidents to which members of the U.S. public are generally exposed. This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG3 value is $1x10^{-6}$ /yr.*

***Individual Worker Acute** (QHG 4): A risk to a worker of a prompt fatality due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one percent of the prompt fatality risk in all higher risk industries. This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG4 value is $1x10^{-6}$ /yr.*

***Individual Worker Latent** (QHG 5): A risk to a worker of a latent cancer fatality due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one percent of the latent cancer fatality risk in all higher risk industries.*

This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG5 value is $1x10^{-5}$ /yr or 25 mrem/yr.

<u>Individual Worker Injury</u> (QHG 6): A risk to a worker of severe injury due to inadvertent or accidental exposure from nuclear material and waste activities should not exceed one percent of the severe injury risk in all higher risk industries. This could be regarded as "negligible additional risk" in risk-informed decisions. The draft QHG6 value is $5x10^{-6}$ /yr.

5.3 Rationale for Qualitative and Quantitative Risk Guidelines

In developing the above qualitative and quantitative guidelines, careful attention was given to the following:

- The spectrum of NMSS/FSME-regulated facilities and activities and the nature of the risks they represent; and
- The methods NMSS/FSME used, first to understand the Commission's use of the logic and reasoning in the reactor SGPS to define and outline the basis for the reactor safety goals and QHOs, and then to appropriately adapt and modify these goals and objectives to derive QHGs for the diverse NMSS/FSME-regulated facilities.

The principle underlying the development of ***qualitative*** risk guidelines for the public is the notion that nuclear facilities and activities should not impose a significant additional risk on the public beyond the risks that people experience in their daily lives. In the SGPS, the Commission expressed this qualitatively as "*...such a level of safety that individuals living or working near nuclear power plants should be able to go about their daily lives without special concern by virtue of their proximity to these plants*." Translated to NMSS/FSME-regulated facilities and activities, this principle would imply that individual members of the public who live or work or find themselves in proximity to such facilities, or places where such activities are conducted, should face a negligible additional risk by virtue of their proximity.

The Commission went further, in the SGPS, by providing a ***quantitative*** dimension to the definition of "insignificant" and "proximity." In this way, the qualitative goal of negligible additional risk to the public from NPP operation was transformed into two quantitative risk objectives, one for the risk of a prompt fatality (that could potentially occur from large accidental radioactive releases) and the other for the risk of a latent-cancer fatality (that could occur from accidental releases of all magnitudes).

The Commission defined negligible as one-tenth of one percent (0.1 percent) of the background mortality risk, either of prompt fatality or of fatal latent cancer, which people face in the U.S. The Commission felt that the ratio of 0.1 percent to other risks commonly faced in society is "*...low enough to support an expectation that people living or working near nuclear power plants would have no special concern due to the plant's proximity*."

The same definition of negligible additional risk has been adopted for QHG 1 and QHG 2 (i.e., 0.1 percent of the background risk that represents, respectively, the risk of prompt fatality and latent cancer fatality for members of the public from accidents at NMSS/FSME-regulated facilities and activities). The Commission has already defined this level in the SGPS, as representing a level of safety such that individual members of the public should have no special concern about being in the vicinity of nuclear facilities or activities that achieve this level. Hence, in the interest of consistency and to create a "level playing field" for applying RIDM to all NRC activities for the metric of public health and safety, it was deemed appropriate to choose one-tenth of one percent of the relevant background risk as a standard for judging "negligible" additional risk in the formulation of QHG 1 and QHG 2.

A ***qualitative*** deterministic radiation injury goal for the general public was not defined in the SGPS. This is a level of exposure to ionizing radiation that is severe enough to cause radiation burns, or other symptoms of severe radiation injury, but lower than the threshold dose needed to cause a prompt fatality. Toxic chemical effects of accidents involving licensed materials can also result in serious injury. Such deterministic exposures will also greatly increase the risk of a latent cancer fatality. To set a guideline for this accidental outcome, the same approach was adopted as used in the prompt fatality and latent cancer fatality outcomes (viz., that the risk of a deterministic exposure leading to a severe radiation (or chemical) injury from accidents at NMSS/FSME-regulated facilities and activities should be a negligible additional risk for individual members of the public). Transforming this into the QHG 3 is provided again by the criterion of 0.1 percent of background risk of severe injury to the U.S. population from all other causes.

The notion of the aforementioned "proximity" is defined in relation to both the risk metric under consideration and the population that is at significant risk, with regard to the consequence encompassed by that particular metric.

For the individual risk of prompt fatality, the Commission defined proximity in the SGPS in terms of the population within 1.6 km (1 mile) of the plant boundary, based on the following reasoning (Ref. 5.1):

> *In applying the objective for individual risk of prompt fatality, the Commission has defined the vicinity as the area within 1 mile of the nuclear power plant site boundary, since calculations of the consequences of major reactor accidents suggest that individuals within a mile of the plant site boundary would generally be subject to the greatest risk of prompt death attributable to radiological causes.*

For latent cancer fatality, the Commission chose the population at risk as the population within 16 kms (10 miles) of the plant by reasoning that (Ref. 5.1):

> *The bulk of significant exposures of the population to radiation would be concentrated within this distance [i.e., 10 miles), and thus this is the appropriate population for comparison with cancer fatality risks from all other causes. This objective would ensure that the estimated increase in the risk of delayed cancer fatalities from all potential radiation releases at a typical plant would be no more than a small fraction of the year-to-year normal variation in the expected cancer deaths from non-nuclear causes.*

Based on the above reasoning, it is clear that the Commission chose to define "proximity" (i.e., the population at risk) by taking into account two factors, one factor being causation (viz., that the death should be "attributable" to radiological causes), and the other being the population subject to the "greatest" or most "significant" risk, depending on the risk metric involved. The Commission specifically referred to the experience gained from "*...calculations of the consequences of....accidents*," which suggests that the distances (and the populations at risk) were not chosen arbitrarily but were selected on the basis of reactor probabilistic risk assessments or at least consequence assessments.

The above reasoning can be applied to NMSS/FSME risk guidelines, to determine what factors are important in influencing the population most at risk from an accident at the different and very diverse NMSS/FSME-regulated facilities and activities. It is clear that the population at risk will be very different, depending on the particular facility and activity involved. The nature and kind of risk posed by large stationary nuclear facilities, such as fuel fabrication plants, where the general public is excluded from routine access by a boundary or exclusion zone, must be distinguished from the risk of small, sealed calibration and check sources in laboratories or industrial facilities that emit radiation to which the public can potentially be exposed. The factors that are important in determining the population at significant risk for various NMSS/FSME-regulated facilities and activities are discussed further in Section 5.5.

The proposed draft risk guidelines for NMSS/FSME-regulated facilities and activities apply to workers as well as the public. There are no worker-risk guidelines and corresponding QHGs for workers in the reactor SGPS. Therefore, there is no analog of Commission prior guidance that could be considered, in principle, to develop a quantitative risk guideline similar to the guideline of 0.1 percent of the background risk of prompt fatality and latent cancer fatality for the general public stated above. Accordingly, the development of a basis for defining quantitative risk guidelines for workers has taken into account the following elements: (1) the actuarial data across all industries and occupations of the risk of fatality; (2) health risk guidelines developed by the United Kingdom Safety and Health Executive for workers in the nuclear industry (Ref. 5.4); (3) the existence of regulations embodied in 10 CFR Part 20 and the principle of ALARA that serve to strictly regulate worker exposure; (4) the safety record achieved by the U.S. nuclear industry in protecting its employees from the risks of acute radiation exposures; and (5) the notion of voluntary risk that industry workers embrace in return for compensation as contrasted with the involuntary risk faced by the public.

Based on these considerations, a suitable criterion for establishing a worker risk guideline is believed to be as follows: that the additional risk of prompt fatality from accidents involving acute exposure to ionizing radiation faced by a worker in the nuclear industry should be "small" in comparison to the risks of prompt fatality faced by U.S. workers generally (i.e., not so small as in the case of members of the public who usually are not properly trained in radiation protection, but still small), since all radiation workers are required to be properly trained. This concept also acknowledges the generally good safety record of the regulated nuclear industry and the aspiration of maintaining it at a high level.

A quantitative dimension to the concept of "small," that transforms the worker prompt fatality guideline into a QHG, is determined to be about 2 percent of the background fatality risk faced by workers across all industries and occupations or, equivalently, 1 percent of the fatality risk in the higher-risk industries, such as mining and transportation. This serves to define QHG 4.

Worker exposure to stochastic doses of radiation is regulated under 10 CFR Part 20, which establishes annual limits on exposure from licensed operation and also mandates the principle of ALARA, taking into account technology, cost, and related considerations. As stated above, the guideline for worker latent cancer fatality is only meant to apply to exposures that are unplanned, inadvertent, or accidental. The criterion used for establishing the worker risk guideline in this area is that the additional risk of latent cancer fatality should be "small" in comparison to the annual risk of cancer faced by the U.S. population.

A quantitative dimension to the concept of "small" that transforms the worker latent cancer fatality guideline into a QHG is estimated to be about 0.5 percent of the background latent cancer fatality risk faced by the U.S. population. Because there is no precedent for this figure, it is proposed for further discussion and use. This serves to define QHG 5.

The deterministic radiation injury risk goal for workers is also established on the basis that the risk of accidental exposure to a dose of ionizing radiation that could result in a severe injury, but not a prompt fatality, should be "small." The criterion for establishing a quantitative value of this risk is that it should lie between the risk of prompt fatality, which is caused by very large radiation exposure, and the risk of a latent cancer fatality, caused by a stochastic dose of radiation; namely, that the deterministic exposure risk guideline should be set at a more stringent level than the stochastic exposure risk guideline, but at a less stringent level than the prompt fatality risk guideline. This helps to define the proposed value for QHG 6.

5.4 Data on the Background Risks Used to Develop Base Quantitative Health Guidelines

5.4.1 Public – Quantitative Health Guidelines 1, 2, 3

As stated above, the values of the QHGs for the general public (QHG 1, QHG 2, and QHG 3) have been selected based on the concept of "negligible additional risk," defined to be 0.1 percent of the background risk of prompt fatality, latent cancer fatality, and severe deterministic injury, respectively, that is faced by the U.S. population.

Data for the year 2000 on the background risks of prompt fatality and severe injury have been taken from the WISQARS™ (Web-based Injury Statistics Query and Reporting System) website of the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention (Ref. 5.5). Data on the background risk of a latent cancer fatality have been taken from publications of the National Cancer Institute of the Centers for Disease Control and Prevention (Ref. 5.6).

Accidental fatalities in the U.S. for the year 2000, for all races and sexes and from all causes, amounted to 148,209 out of a total population of 275 million, to provide a rate of approximately 5.3×10^{-4}, rounded off to 5×10^{-4} /yr. QHG 1 is 0.1 percent of this background rate, which yields a figure of 5×10^{-7} /yr.

Cancer fatalities across all races and sexes in the year 2000 occurred at a rate of about 2×10^{-3} /yr. QHG 2 is 0.1 percent of the background rate, which gives a value of 2×10^{-6} /yr which is equivalent to 4×10^{-3} rem/yr.

Severe, nonfatal injury is defined in the database of the National Center for Injury Prevention and Control to be a bodily harm resulting from severe exposure to an external force or substance (mechanical, thermal, electrical, chemical, or radiant) or a near-drowning. WISQARS™ bases its definition of a nonfatal injury on data from hospital emergency departments and contains information on injuries by various causes and intent, and by sexes, races, and disposition. The last category refers to the status of the injured person at the time of release from the emergency department and includes: (1) treated and released; (2) hospitalized; (3) transferred to a specialized trauma center or a rehabilitation unit; (4) transferred and hospitalized; and (5) observed or unknown. Category (3) was selected to serve as the appropriate background rate for severe injury (comparable to a deterministic radiation injury that could result in a permanent disability). The background rate for the year 2001 for all sexes and ages in this category is 1.1×10^{-3} /yr. QHG 3 is 0.1 percent of the background rate, which gives a value of 1×10^{-6} /yr.

5.4.2 Workers – Quantitative Health Guidelines 4, 5, 6

The quantitative health objective (QHO) for limiting worker exposure that could lead to an early fatality is based on examining data on worker fatalities in industry generally. Industry data on the rate of worker fatalities across all industries and occupations in the U.S. were obtained from the website of the Bureau of Labor Statistics (Ref. 5.7) and are shown in Table 5.1.

Focusing on Table 5.1, it is seen that the average fatality rate across all occupations in the U.S. is 4.4×10^{-5} /yr, or approximately 5×10^{-5} /yr. The higher-risk occupations such as transportation, manufacturing, and construction have a rate that is about twice the average rate (7.5×10^{-5}), or about 1×10^{-4} /yr.

Table 5.1. Numbers and Rates of Fatal Occupational Injuries by Industry Division, 2000

Industry Group	Number of Fatalities 2,3	Fatality Rate 1 (per 100,000 employed)
Construction	1,154	12.9
Transportation	957	11.8
Services	768	2.0
Agriculture	720	20.9
Manufacturing	668	3.3
Retail Trade	594	2.7
Government	571	2.8
Wholesale Trade	230	4.3
Mining	156	30.0

Finance	79	0.9
TOTAL	**5,915**	**4.4**
Agriculture, Mining, Construction, Transportation, Manufacturing	3655	15.8

Source: Refs. 5.7, Circa 2000.

Notes:
1. Rate = (Fatal work injuries/Employment) x 100,000 workers. Employment data extracted from the 2000 Current Population Survey.
2. Total for categories includes subcategories that are not included in the category amount.
3. The fatality rates were calculated using employment as the denominator; employment-based rates measure the risk for those employed during a given period of time, regardless of exposure hours.

The proposed QHG 4 for the risk of early fatality is set at $1x10^{-6}$ /yr; this is approximately 2 percent of the risk in all industry (it is about 1 percent of the risk in the higher-risk industries of agriculture, mining, transportation, manufacturing, and construction industries, combined). Compared to the public early fatality QHG 1 of $5x10^{-7}$ /yr, QHG 4 is about twice the proposed value of QHG 1. This feature is consistent with the notion of voluntary risk; namely, that the worker, by virtue of his/her employment, should bear a somewhat higher risk than a member of the general public, who is not being compensated for the risk and has not received any training in averting the risk.

QHG 5 is based on the worker risk of developing latent cancer from accidental exposure. As stated above, the proposed guideline is to limit the worker risk to 0.5 percent of the background spontaneous cancer risk of $2x10^{-3}$ /yr, to give a latent cancer health guideline of $1x10^{-5}$ /yr which is equivalent to $2.5x10^{-2}$ rem/yr.

Data on the background risk of severe injuries to workers in industry are under development at this time. Preliminary indications are that the background risk may be in the range of 1 in 1000 per year and the proposed guideline of 0.5 percent of background would imply a risk of $5x10^{-6}$ /yr.

The basis on which worker QHGs should be developed is an issue that needs more discussion and is ultimately a policy decision. One dimension of the policy issue in this area is whether NRC guidelines might conflict with the safety approach of OSHA or MSHA.

On nonradiological (hazardous chemical) risk in facilities regulated by NMSS/FSME, it should be noted that a significant component of the risk in facilities governed by 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" comes from chemicals, as does the risk in activities, such as uranium recovery, licensed under 10 CFR Part 40. Uranium recovery is also subject to MSHA regulation. In fact, NRC has interagency agreements with a number of other agencies (both Federal and State) in activities subject to NMSS/FSME regulation. One issue is whether adoption of risk guidelines that include chemical risk might lead to problems of overlapping jurisdiction. However, NRC does impose safety limits and standards, and the

adoption of guidelines may enhance the coherence of the regulatory process by focusing attention on the risks that are more significant in any particular area.

Similar to the public injury QHG 3, the objective of the worker injury QHG 6 is to provide a risk guideline for accidental exposure to levels of ionizing radiation (or toxic chemical effects of licensed material) that can cause severe injury (e.g., radiation burns) but are below the threshold for early fatality. There is a significant amount of actuarial data on worker injuries from exposure to radiation in applications such as radiography. The exposures arise mainly from accidents involving loss of source control from human error or equipment failure.

QHG 6, for worker injury, is set at $5x10^{-6}$ /yr. This proposed value lies between the worker early fatality QHG 4, of $1x10^{-6}$ /yr, and the proposed worker latent cancer QHG 5, of $1x10^{-5}$ /yr. This value allows for a consistent set of worker QHGs based on the magnitude of exposure levels. In other words, the early fatality dose levels (e.g., > 200 rem doses) have the most stringent QHG 4 of $1x10^{-6}$/yr, the injury dose levels (e.g., > 50 rem) have a QHG 6 of $5x10^{-6}$/yr, and lower stochastic doses have a QHG 5 of $1x10^{-5}$ /yr.

5.5 Population at Significant Risk

In the preceding section, six QHGs were defined in terms of benchmark values of risk metrics. These risk metrics can be calculated, in principle, via a probabilistic risk assessment of a particular facility or activity and then compared with the QHGs to establish the risk of a particular facility or activity with respect to the value of the QHG. The following offers a discussion of the factors affecting the calculation of the risk metrics in particular facilities, applications, and/or areas shown in Table 5.1, to compare with the values of the corresponding QHGs. The objective of the calculation would be to determine, within the context of a PRA of a particular facility or area, the baseline value of a particular risk metric with respect to the value defined by the QHG. The general approach taken for evaluating individual risk is similar, in principle, to that specified by the Commission in its SGPS for calculating the values of the commercial power reactor QHGs. This approach basically consists of identifying the relevant “population at significant risk” that is appropriate to the risk metric under consideration and then evaluating the risk to an "average individual" within that population.

For the purpose of comparing the risk from a specific NMSS/FSME-regulated application with the QHGs, it is important to recognize that the risk should be calculated on a realistic basis and not with conservative assumptions regarding the parameters entering the risk calculation. Such parameters would be the phenomenology of the accident scenarios, the frequency of their occurrence, the estimation of consequences (i.e., radiation doses or chemical exposures leading to acute fatalities, latent cancers, and severe injuries), and the population at significant risk for various consequences. In this regard, it is important to distinguish between the estimation of risk for purposes of comparison with the risk guidelines and the estimation of consequences for other regulatory purposes, such as licensing actions that involve the evaluation of compliance with various types of regulatory dose limits. In the latter case, conservative assumptions are rightly used to establish compliance with regulations, and the calculation is carried out in a prescriptive manner. It is noted that the regulations consider accidents in a prescriptive fashion (e.g., regulations pertaining to design-basis accidents). A risk assessment should consider all realistic accident scenarios.

The purposes of carrying out a risk assessment, to compare the result with the risk guidelines and thus gain risk insight, is different from establishing regulatory compliance. The purpose is to understand the magnitude of the risk presented by an operating system and compare it to a reference level represented by the risk guideline. For this reason, it is important to carry out the calculation in as realistic a manner as possible, with, of course, allowance for incorporating all the uncertainties. The purpose of estimating this risk for decisionmaking is to evaluate the significance of changes or exemptions, to determine if further risk reduction is warranted, or to arrive at a basis for regulatory resource allocation decisions.

The full-risk spectrum has to be considered, along with the population that is at significant risk for a defined consequence. The analogy with the QHOs that were defined in the (reactor) SGPS is to estimate the risk to the average individual, within the population, that is at significant risk for that particular health outcome.

Hence,

T*he average individual risk of an acute fatality is*:

*= ∑ (Freq. of accident I) * (number of acute fatalities from accident i)/Total population at significant risk for acute fatality... (1)*

The average individual risk of a severe injury is:

*= ∑ (Freq. of accident I) * (number of severe injuries from accident i)/Total population at significant risk for severe injury.... (2)*

And the average individual risk of latent cancer is:

*= ∑ (Freq. of accident I) * (number of latent cancers from accident i)/Total population at significant risk for latent cancer..... (3)*

Since an acute fatality and a severe injury both involve dose thresholds (approximately 200 rem whole body (WB) in the case of acute fatality, and, 50 rem WB (proposed) in the case of severe injury), it is possible, in principle, although it may be difficult in practice, to establish the denominator for [1) and [2) above, for calculating the average individual risk within the population at significant risk. However, given the linear, no-threshold model for latent cancer, some criterion has to be developed for establishing a denominator for [3). Such a criterion can be based on criteria similar to the reasoning given by the Commission in the (reactor) SGPS for choosing the population out to 1.6 km (1 mile) as the population at risk for purposes of calculating the early-fatality QHG and the population to 16 kms (10 miles) as the population at significant risk for calculating the latent-cancer QHG. Hence, both the numerators and denominators in [1) and [3) were taken to 1.6 and 16 kms (1 and 10 miles), respectively, and the SGPS risks were understood as the average risks to individuals within 1.6 and 16 kms (1 and 10 miles), respectively. This does not mean that the populations outside these distances had zero risk. However, the estimated individual risk within the 1.6 and 16 kms (1 mile and 10 mile zone) represents the maximum level.

Section 5.5.1 provides some examples of risk assessment results using various quantitative risk metrics for comparison with corresponding risk guidelines. These estimates were based on readily available information, and may benefit from a more refined treatment consistent with the principles discussed above. However, they provide examples of the issues involved in the calculation, in particular, the selection of the population at significant risk, to estimate average individual risk. The data on which these preliminary calculations are based are of varying vintage and quality. Section 5.5.1 is focused on calculating risk for three materials facilities/activities that were assessed in the Integration Study Report (Ref. 5.2).

5.5.1 Estimation of Risk Metrics for Selected Materials Systems

A detailed assessment of risk from 40 materials subsystems was carried out in NUREG/CR-6642 (Ref. 5.8). The results from that study have been used to explore various approaches for calculating risk for comparison with the proposed QHGs for the three materials device/systems that were also analyzed in the case study. These three device/systems are: gas chromatographs, static eliminators, and fixed gauges (gamma and beta). As far as public risks are concerned, there were no accidents identified that can lead to early fatality (i.e., no accidents where the dose would exceed the threshold for early fatality). Hence, the public risk of acute fatality from all three devices is zero for purposes of comparison with QHG 1, the risk guideline for early fatality, with a value of $5x10^{-7}$ /yr. Data on accidents where the dose could exceed the severe-injury threshold (tentatively identified as 50 rem WB) were not available; hence, the public risk of severe injury for comparison with QHG 3 was not calculated.

For comparison with QHG 2, the latent cancer risk guideline with a value of $2x10^{-6}$ /yr, data are available from NUREG/CR-6642 on the public risk of dose on both a per-facility and an industry-wide basis. This is presented as an expected value (assumed to be a product of frequency and dose summed over all accidents) in mrem/yr. This is shown in Table 5.2 for the three devices in the case study.

Table 5.2. Public Accident Risks from Byproduct Materials Systems in the Case Study (Based on data from NUREG/CR-6642)

Material System	Public Risk (mrem/year)		Dominant Accident Cause
	Per-Facility	Industry-wide	
Gas Chromatographs	$2.6x10-^{3}$	$1.2x10^{1}$	Lost or stolen sources; approx. 120,000 devices
Fixed gauges (gamma)	$2.4x10^{-2}$	$2.9x10^{3}$	Lost or stolen sources; approx. 40,000 devices
Fixed gauges (beta)	$5.7x10^{-4}$	$3.1x10^{1}$	Lost or stolen sources; approx. 100,000 devices
Static eliminators (assumed to be about 10% of all small sealed sources)	$1.7x10^{-4}$	$1.2x10^{2}$	Lost or stolen sources; approx. 75,000 static-eliminator devices

By using the BEIR-V conversion factor, which for the public is $5x10^{-4}$ latent cancers per rem, the expected value of dose can be converted into latent cancers per year. However, for purposes of comparison with QHG 2, a figure for the population at significant risk is needed. If the accidental exposure of the public is from a lost or stolen source, as it is, in fact, for all the devices studied, then some basis has to be developed for estimating the population that is at risk of exposure. The related question, of course, is what are the assumptions underlying the figure for public risk presented in Table 5.1? Does this represent average individual risk, in some sense, or is it calculated on the basis that only one individual receives (or can receive) the accidental dose? In other words, if the figures presented in NUREG/CR-6642, the most detailed risk study of materials to date, have to be used to calculate the risk for comparison with QHG 2, a clear understanding of their basis has to be arrived at to use them in this particular context. Until such understanding is established, an interim approach is taken, as discussed below.

A few initial approaches have been developed for use in this report, mainly to serve as a basis for further discussion and elucidation:

(1) One approach (Approach 1) is to assume that the per-facility public risk reported in Table 5.1 represents the risk to just one person who is inadvertently exposed as a result of mishandling a lost source from a facility. The industry-wide risk is assumed to represent the aggregate risk over all facilities. The industry-wide population at risk is then obtained from the per facility population at risk by looking at the data on the total number of devices, and estimates of the average number of devices per facility.

(2) Another approach (Approach 2) is to evaluate the public population at risk on a per-facility basis alone. This approach assumes that the facility is located in a small town of approximately 10,000 population, and the risk arises from the lost or stolen source getting into the waste stream. In this approach, the entire population of the town is considered to be potentially at risk of exposure. Conceptually, this approach to identifying the population at risk represents a very different situation compared to the stationary facilities, such as fuel fabrication plants. Since the materials devices only have a small radioactive inventory, actual radiation risk can only be to the person (or members of his/her family) who inadvertently picks up a lost device. (This is unlike the plume exposure from accidents at a large facility that can affect many offsite people.) However, since the whole town has potential access to a lost source, in one sense, the entire population can be considered to be at risk.

(3) A third approach (Approach 3) is to evaluate the public population at risk on an industry wide basis only by using the annual loss rate for these devices nationwide (approximately six devices per year) and assuming that the loss occurs in different small towns, each with an average population given in Approach 2. This approach is similar to Approach 2 except that the numerator in the average individual-risk calculation is based on the industry-wide estimate in Table 5.1.

The results of these calculations of the average individual risk of latent cancer, using each of the above approaches, are shown in Table 5.3.

Table 5.3. Average Public Individual Risk of Latent Cancer Based on Different Approaches for Estimating the Population at Risk

Device/Facility	Average Individual Risk of Latent Cancer (per year) (QHG 2 = $2x10^{-6}$/year)			
	Approach 1		Approach 2	Approach 3
	Per-Facility Basis	Industry-Wide Basis	Per-Facility Basis Only	Industry-Wide Basis Only
Gas Chromatographs Total: 120,000 number/facility = 10	$1.3X10^{-9}$	$5X10^{-10}$	$1.3X10^{-13}$	$1x10^{-10}$
Static Eliminators Total: 75,000 number/facility = 5	$8.5X10^{-11}$	$4X10^{-9}$	$8.5X10^{-15}$	$8x10^{-10}$
Fixed gauges (gamma) Total: 40,000 number/facility = 2	$1.2X10^{-8}$	$7.2X10^{-8}$	$1.2X10^{-12}$	$1.5x10^{-8}$
Fixed gauges (beta) Total: 100,000 number/facility = 5	$2.9X10^{-10}$	$7.8X10^{-10}$	$2.9x10^{-14}$	$1.6x10^{-10}$

The results for the individual risk of latent cancer calculated, using the different approaches for the population at risk shown in Table 5.3, are broadly similar for Approaches 1 and 3. The results using Approach 2 are much smaller because the per-facility risk estimate from NUREG/CR-6642 is now being distributed over a much larger population. All the computed risk values, however, fall below the QHG 2 risk guideline value of $2x10^{-6}$ /yr.

NUREG/CR-6642 also contains estimates for worker risk both on a per-facility and an industry-wide basis, for the systems/devices analyzed in the case study. For gas chromatographs, static eliminators, and fixed gauges (beta), no accident sequences (down to a frequency of $5x10^{-7}$/yr) were identified that could lead to an early fatality. However, for fixed gauges (gamma), there is an identified accident sequence consisting of a device damaged by a crushing event that causes failure of the shielding and encapsulation. This accident sequence can lead to a dose of almost 600 rem (WB) that is considerably in excess of the threshold for early fatality. The frequency of this sequence is estimated at $1.8x10^{-6}$ /yr. The population at risk is assumed to be, on average, two workers per facility. This is the population at risk for acute fatality. Hence, the average individual risk of acute fatality is estimated to be $9.0x10^{-7}$ /yr. This can be compared with the proposed worker early-fatality risk guideline of $1x10^{-6}$ /yr.

Data on accidental doses that could lead to a risk of severe injury to workers were not available. However, data on smaller accident doses that could lead to a risk of latent cancer are provided in NUREG/CR-6642, on both a per-facility and an industry-wide basis. These are shown in Table 5.4.

Table 5.4. Worker Accident Risks from Byproduct Materials Systems in the Case Study (Based on data from NUREG/CR-6642)

Material System	Worker Risk (mrem/year)		Dominant Accident Cause
	Per-Facility	Industry-wide	
Gas Chromatographs	$2.8X10^{-3}$	$1.2X10^{+2}$	Leaking or damaged source
Fixed gauges (gamma)	$3.1X10^{-2}$	$4.5X10^{+4}$	Leaking source or shielding failure from fire
Fixed gauges (beta)	$4.5X10^{-4}$	$2.3X10^{+1}$	Leaking source or shielding failure from fire
Static eliminators (assumed to be about 10% of all small sealed sources)	$1.2X10^{-5}$	$1.9X10^{+2}$	Leaking or damaged source

To compute the average individual risk of latent cancer for the workers, and to compare it with the proposed latent cancer QHG, an estimate of the worker population at significant risk is needed. Although this is likely to differ among industries, it is assumed, for purposes of discussion, that the average number of workers at risk per facility is two and the average number at risk on an industry-wide basis is 10,000. Using these assumptions, the average individual risk of latent cancer calculated using the worker risk coefficient of $4x10^{-4}$ latent cancers per rem is shown in Table 5.5.

Although all the average individual risks of latent cancer for workers are considerably below the risk guideline of $1x10^{-5}$ /yr, the differences between the risks calculated on a per-facility and industry-wide basis, especially for static eliminators and fixed gauges (gamma), need to be understood. These are likely to be caused by the differences between the way in which the estimates in NUREG/CR-6642 were generated and the assumptions used in estimating the number of workers at risk for these materials and devices.

Table 5.5 Average Individual Risk of Latent Cancer for Workers

Material System/Device	Average Individual Risk of Latent Cancer (per year) QHG 5 = 1X10-5/yr	
	Per-facility basis	Industry-wide basis
Gas Chromatographs	$5.6X10^{-10}$	$4.8X10^{-9}$
Static Eliminators	$2.4X10^{-12}$	$7.6X10^{-9}$
Fixed gauges (gamma)	$6.2X10^{-9}$	$1.8X10^{-6}$
Fixed gauges (beta)	$9.0X10^{-11}$	$9.2X10^{-10}$

5.5.2 Estimation of Risk for Fuel Cycle Facilities

(Reserved for future use)
(Reserved for Table 5.6)

5.5.3 Summary

The factors that affect the population at risk for various health outcomes at the very different kinds of facilities and activities regulated by NMSS/FSME have been discussed in Section 5.5. From the standpoint of risk estimation, the facilities and activities are divided into three categories: (1) stationary facilities, such as the fuel cycle facilities, with comparatively large inventories of radioactive and hazardous chemical materials; (2) activities involving storage and transport of radioactive materials, including reactor spent fuel; and (3) industrial and medical facilities and activities using radioactive materials. Various issues that affect the nature and kind of risks presented by these facilities, to both the offsite public and the onsite workers, were discussed and elaborated previously.

Section 5.5 presents risk data and an estimation of the QHGs for selected facilities and activities. In Section 5.5.1, available risk data from NUREG/CR-6642 are presented for three specific materials systems: gas chromatographs, static eliminators, and fixed gauges (beta and gamma), which were studied earlier in the case studies presented in the Integration Report (Ref. 5.2). These data are then combined with a number of assumptions regarding the population at risk from these devices to calculate the risk measures, average individual risk of early fatality, and average individual risk of latent cancer for both the public and the workers. A number of issues emerge from this preliminary exercise:

(1) For the three materials systems examined, the only early fatality risk identified is to workers from accidents involving fixed (gamma) gauges that use americium-241 (Am-241); the other systems/devices have too low an inventory of radioactive material to pose an early-fatality risk.

(2) NUREG/CR-6642 is a rich source of data, but the information is not completely available in the printed reports; more interaction between the authors and users would be useful in developing a firmer base for selecting among the various approaches identified for estimating the population at risk in specific activities.

(3) Data corresponding to the severe-injury outcome were not available either for workers or the public.

(4) The estimation of latent cancer risks for both public and the workers shows that the risks fall below the corresponding risk guidelines QHG 2 and QHG 5, in some cases, by several orders of magnitude. These calculations reinforce the conclusions that were reached in the case studies reported in the Integration Report.

5.6 Draft Risk Guidelines - Other Approaches for Consideration

The discussion on the draft risk guidelines thus far has focused on the base approach. Per recommendations from Ref. 5.9, other alternative approaches are being evaluated. Meanwhile, other policy and implementation issues (see Appendix I) are also being considered.

5.7 International Activities on Safety Goals and Risk Guidelines

The results of a survey of information and activities relevant to the development of risk guidelines in the materials and waste arenas were reported in Ref. 5.10. This reference contains the results of a search of the international literature on safety-goal development. While there is a particular focus on information from Japan and the U.K., a broad search across many other countries has also been performed. Discussions were held with various individuals who were knowledgeable about the objectives of this program. Documents were gathered and reviewed from readily available sources (libraries and the web). Cognizant safety experts in several countries were contacted to obtain relevant current information on the subject area. These sources do not have the same approach to regulation or radioactive material as does NRC. However, they are useful in obtaining comparative insights for safety guideline development.

This literature review determined that much material exists, in several countries and organizations, that is useful to constructing risk guidelines in the materials and waste arenas. It should be noted that this review was not exhaustive. As additional information becomes available, it should be considered in the development of the risk guidelines, as appropriate.

The work in the U.K. is reasonably mature and many relevant ideas exist in that body of work. The work in the field of radiation protection carried out by such standards-setting organizations as the International Commission on Radiation Protection (ICRP), the National Council on Radiological Protection and Measurements, and the National Academy of Sciences form an important foundation for risk-guideline development, and due consideration should be given to that material. Other countries, such as Japan, have taken some steps toward safety-goal development for power reactors, but less so for materials and waste. There is some helpful material on the key issues relevant to this program (e.g., worker/public, accident/normal, individual/societal risk). However, the specific application of this information to these issues and the tailoring of the ideas to the NMSS/FSME-specific regulatory environment is not directly evident.

ICRP has developed a conceptual framework (Ref. 5.11) for protection from potential exposure. This document extends the ICRP philosophy of radiation protection (Ref. 5.12) to the accident regime by considering nonroutine exposures and their likelihoods. ICRP distinguishes between normal exposure and potential exposure by regarding the former as those exposures that are reasonably expected to occur (planned plus unintended high-probability, low-consequence events). ICRP regards potential exposures as uncertain events that fall outside the general boundaries considered for normal exposure. For the risk to individual health from potential exposures, ICRP *"...recommends that limits of risk be the same order of magnitude as the health risk implied by the dose limits for normal exposures."* This concept and the range of probabilities vs. health effects to the individual are broadly consistent with the approach and

recommendations of this report. For the convenience of the reader, the range of (annual) probabilities, suggested by ICRP, for four health impacts on the individual, are shown in Table 5.7.

Table 5.7. ICRP 64 Framework for Potential Exposures

Health Impact	Annual Probability Range
Treated as Normal Exposures	$1x10^{-1}$ to $1x10^{-2}$
Stochastic Effects, but above Dose Limits	$1x10^{-2}$ to $1x10^{-5}$
Some Radiation Effects are Deterministic	$1x10^{-5}$ to $1x10^{-6}$
Death is Likely to Result	$< 1x10^{-6}$

5.8 References

5.1 U.S. Nuclear Regulatory Commission, “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement,” Federal Register, Vol. 51, p. 30028 (51 FR 30028), August 4, 1986.

5.2 U.S. Nuclear Regulatory Commission, “Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments,” ADAMS Accession Number ML 022130067, February, 2002.

5.3 U.S. Nuclear Regulatory Commission, “Staff Requirements - SECY-99-100 - Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards,” June 28, 1999.

5.4 United Kingdom Health and Safety Executive, “Safety Assessment Principles for Nuclear Plants,” ISBN 0 11 882043 5, 1992, http://www.hse.gov.uk/nsd/saps.htm.

5.5 WISQARS, "Web-based Injury Statistics and Query Reporting System," Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, http://webapp.cdc.gov/ncipc/wisqars.

5.6 National Cancer Institute, "2001 Cancer Progress Report," National Institutes of Health, U.S. Department of Health and Human Services, Washington, DC, 2002.

5.7 United States Department of Labor, Bureau of Labor Statistics, http://www.bls.gov.

5.8 U.S. Nuclear Regulatory Commission, “Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,” NUREG/CR-6642, February 2000.

5.9 Advisory Committee on Nuclear Waste, Letter to Commission, dated June 9, 2004.

5.10 Letter report, “International Activities on Safety Goal Development,“ Brookhaven National Laboratory, June 6, 2002.

5.11 International Commission on Radiological Protection, “Protection from Potential Exposure: A Conceptual Framework,” ICRP Publication 64, 1993.

5.12 International Commission on Radiological Protection, “Recommendations of the International Commission on Radiological Protection,” ICRP Publication 60, 1991.

6 RISK COMMUNICATION

6.1 Introduction

To be effective in communicating risk-informed decisions, it is important to consider early in the process who needs to be informed and involved, as well as who will be impacted, and to build in communication steps that encourage discussion and clarification throughout the process.

A communication plan should be developed as one of the early activities. Potential internal stakeholders (e.g., line and senior management, other divisions or offices, etc.) and external stakeholders (other government agencies, industry, affected state and local governments, affected citizens, etc.) should be identified if they may use or be impacted by the risk. This enables analysts and decision-makers to be prepared for communication activities during and at the end of this risk-informed process. Placing emphasis on communication during the process will help identify topics that require clarification by the staff and focus attention on ensuring that all participants share an understanding of the subject, objective, terms, and assumptions at hand; this will encourage discussion and prevent misunderstandings among team members and therefore enable everyone to stay on track. This is especially important when working with multidisciplinary teams that include both risk analysts and analysts from other (e.g., engineering and licensing) disciplines. The NRC's Risk Communication Guidelines (Refs. 6.1 and 6.2) emphasize the importance of explicitly addressing communication challenges early in a process. This process follows that guidance and other internal communication guidelines.

In addition, the task of communicating and implementing the decision is where the risk information becomes translated into effective action. The effectiveness of risk information will be limited or non-existent if there is no effective implementation or in cases where stakeholders disagree with the way in which risk information was used. Also, alternatives will typically have risk tradeoffs (e.g., public vs. remedial worker exposures, or trading off larger but low probability hazards for smaller but relatively certain hazards). Therefore, it is important to document and communicate the decision.

6.2 Document the Decision

Once the decision has been made, the staff should document the decision. The analysis report should contain appropriate supplemental material. Documentation of the decision should include not only what the decision was, but also the following:

- Insights obtained from the decision-maker
- How various factors were considered in reaching the final decision
- Factors not considered in the technical analysis of the issue
- Any contingencies or need for subsequent decision points

Decision-makers typically need information presented in summary format for rapid assessment and ease of understanding the impacts and complexity of an issue. However, enough background information should be documented to introduce the issue and the decision that is to be made. The decision that is required should be stated clearly and concisely.

Each of the options developed should be presented individually and concisely. The preferred option should be presented first. The driving factors for accepting or rejecting the option must be presented. Typically these factors address satisfaction or non-satisfaction of the principles of risk-informed decisionmaking that are relevant to the issue, plus a discussion of how the degree of uncertainty (or certainty) of supporting information affects application of the principles to the option. Other relevant criteria must also be addressed, if any. The communication document must provide sufficient information to document the logical basis for accepting and rejecting options.

The logic for accepting the recommended option and not accepting other options must be summarized, drawing from the individual option discussions. Where more than one option is acceptable, the basis for preferring the recommended option must be provided.

Where there are technical issues particularly important for the decision-makers to recognize in order to make a properly informed decision, those issues must be briefly described in the communication document. Decision-makers need narrative descriptions that provide qualitative insight into causes, uncertainties, assumptions, sensitivities and affected outcomes for a given situation. Less information is needed regarding the details of numerical results, statistical methods, and analyses. Other relevant information, such as generic implications, stakeholder concerns, or known or anticipated impacts of a decision on other regulations, should be documented. A list of staff contacts for each relevant issue or input to the document should be provided at the end of the document.

6.3 Communicate the Decision

The decision and related information should be communicated to the various stakeholders in accordance with the Communication Plan developed (Ref. 6.3). The Communication Plan should be examined at this point to ensure that it addresses the right audiences and that the key messages reflect the process and its outcomes. Audiences may include internal and external stakeholders. Key messages may include the information conveyed in the decision communication, as well as background information relevant to specific audiences.

6.4 References

6.1 U.S. Nuclear Regulatory Commission, “Effective Risk Communication—Guideline for Internal Risk Communication,” NUREG/BR-0318, December 2004.

6.2 U.S. Nuclear Regulatory Commission, “Effective Risk Communication—The Nuclear Regulatory Commission’s Guideline for External Risk Communication,” NUREG/BR-0308, January 2004.

6.3 Communication Plan Guidance at: http://www.internal.nrc.gov/communications/plans/guidance.

APPENDIX A

GLOSSARY

APPENDIX A

GLOSSARY

accidental exposure — occupational or public exposure to radiation, chemicals, or other hazardous materials in excess of regulatory limits due to failure or degradation of a system, process, structure, component, barrier, or procedure designed to prevent exposure in excess of regulatory requirements.

ALARA — an acronym for "As Low As Is Reasonably Achievable," meaning that every reasonable effort should be made to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of nuclear energy and licensed materials in the public interest (see 10 CFR Part 20.1003).

backfit — as per 10 CFR Part 50.109(a)(1), “the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedure or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position...” A generic backfit is one that applies to multiple facilities. A plant-specific backfit applies to a single facility and is subject to the requirements of NRC Manual Chapter 0514 and the NRC Guidelines.

Chemical exposure — occupational or public exposure to a licensed material or hazardous chemicals that are used or stored at a NMSS/FSME-regulated facility.

Complementary cumulative distribution function — estimates of the probability that a given consequence will be exceeded.

Consequences — effects of normal and accidental exposures to radiological, chemical, or other hazards resulting from the operation of NMSS/FSME-regulated facilities, activities, and materials.

Critical group — a group of individuals reasonably expected to receive the greatest exposure to residual radioactivity, chemical exposure, or other hazards for any applicable set of circumstances from the operation of NMSS/FSME-regulated facilities, activities, and materials.

Defense in depth — a design and operational philosophy with regard to NMSS/FSME-regulated facilities that calls for multiple layers of protection to prevent and mitigate accidents. It includes the use of controls, multiple physical barriers to prevent release of radiation, redundant and diverse key safety functions, and emergency response measures.

Deterministic radiation exposure — health effects, the severity of which varies with the dose, and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a deterministic effect (also called a nonstochastic effect) (see 10 CFR Part 20.1003).

Event likelihood (highly unlikely, unlikely, likely) — qualitative or quantitative statement of the frequency of occurrence of events at an NMSS/FSME-regulated facility over the licensing period. Classification of occurrence as highly unlikely, unlikely, and likely is defined on an individual facility basis. (See 10 CFR Part 70.61)

Inadvertent exposure — unplanned or unexpected occupational or public exposure to radiation, chemicals, or other hazardous materials in excess of regulatory limits due to failure or degradation of a system, process, structure, component, barrier, or procedure designed to provide exposure in excess of regulatory requirements.

Licensing basis — set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and plant-specific design basis (including all modifications and additions to such commitments over the life of the license). (See 10 CFR 54.3)

Minimal cut set — smallest set of primary events, inhibit conditions, or undeveloped fault events (or combination thereof) which must all occur in order for the top event to occur.

Nuclear material and waste activity — licensed activity or activities being conducted by specific NMSS/FSME -regulated material or waste licensees.

Population at risk — population at, and surrounding, NMSS/FSME -regulated facilities that is at risk of injury and death "attributable" to radiological causes, or subject to the "greatest" or most "significant" risk depending on the risk metric involved.

Potential exposures — potential occupational or public exposure to radiological, chemical, or other risks from the operation of NMSS/FSME -regulated facilities, activities, and materials.

Probabilistic risk assessment — an analytic tool that computes the probability of health, environmental, and economic consequences of events resulting from equipment or human failure. A Level 3 PRA assesses the offsite health effect risk.

Property damage—damage incurred to private or licensee-owned property resulting from an accident at an NMSS/FSME-regulated facility or activity.

Quantitative health guidelines—risk metric values that are "not a significant addition to other risks." The QHGs form a set of minimal risk reference levels for each of the risk metrics used in NMSS/FSME and are applied across all NMSS/FSME-regulated activities.

Quantitative health objectives—quantified restatement of the qualitative risk guidelines that define specific objectives necessary to ensure public and occupational health from the operation of NMSS/FSME-regulated facilities, activities, and materials.

Red Oil- substance of varying composition formed when an organic solution, typically tri-butyl phosphate (TBP) and its diluent, comes in contact with concentrated nitric acid at a temperature

above 120 °C. The solvent TBP is often used to extract uranium or plutonium from acid solutions. Even though red oil is relatively stable below 130 °C, it can decompose explosively when its temperature is raised above 130 °C.

Regulatory limit—specific limitations applicable to actions or effects of NMSS/FSME-regulated activities per regulations contained in Chapter 10 Parts 20, 40, 50, or 72 or other applicable parts of the Code of Federal Regulations, either by direct citation or reference.

Risk (unacceptable, tolerable, insignificant)—quantitative or qualitative assessment of the probability of an accident or event occurring resulting in impacts to public or occupational health or environmental impacts. Insignificant risks result in small impacts on public or worker health or the environment, tolerable risks reflect an increasing probability of occurrence that may require additional oversight or assessment, and unacceptable risks reflect a high probability of occurrence that requires action to rectify the situation.

Risk guidelines—qualitative and quantitative statements designed to guide regulatory requirements in a consistent manner to ensure protection of the public, workers, and the environment from the operation of NMSS/FSME-regulated facilities, activities, and materials. Risk guidelines are not substitutes for NRC regulations or the "defense in depth" principle.

Risk-informed approach— represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A "risk-informed" approach enhances the deterministic approach by: (a) allowing explicit consideration of a broader set of potential challenges to safety, (b) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (c) facilitating consideration of a broader set of resources to defend against these challenges, (d) explicitly identifying and quantifying sources of uncertainty in the analysis (although such analyses do not necessarily reflect all important sources of uncertainty), and (e) leading to better decisionmaking by providing a means to test the sensitivity of the results to key assumptions. Where appropriate, a risk-informed regulatory approach can also be used to reduce unnecessary conservatism in purely deterministic approaches, or can be used to identify areas with insufficient conservatism in deterministic analyses and provide the bases for additional requirements or regulatory actions. "Risk-informed" approaches lie between the "risk-based" and purely deterministic approaches. The details of the regulatory issue under consideration will determine where the risk-informed decision falls within the spectrum.

Risk metric—a more quantitative assessment of risk.

Stochastic radiation exposure—effects that occur by chance, generally occurring without a threshold level of dose, whose probability is proportional to the dose and whose severity is independent of the dose. In the context of radiation protection, the main stochastic effects are cancer and genetic effects.

Subsidiary guidelines—restatement of the quantitative health guidelines to be applicable to specific NMSS/FSME-regulated facilities, uses, or materials.

Subsidiary objectives—restatement of the quantified health objectives to be applicable to specific NMSS/FSME-regulated facilities, activities, or materials.

Unplanned exposure—see Inadvertent Exposure.

Value-impact analysis—an estimate of the benefits (values) and costs (impacts) associated with an action or decision. These should be evaluated in monetary terms when feasible, using qualitative terms where conversion to monetary equivalents is not possible. A value-impact analysis is a substantial part of a regulatory analysis. It may also be described as a benefit-cost analysis.

APPENDIX B

VALUE-IMPACT ANALYSIS

APPENDIX B

VALUE-IMPACT ANALYSIS

As illustrated in Figure 4.1, one outcome of the RIDM application process may be to perform a cost-benefit analysis (value-impact analysis) for new requirements. Detailed instructions on performing this analysis are provided in NUREG/BR-0184, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission." This appendix will provide a generic template for performing the analysis, including a summary of the main attributes. It must be noted that, given the breadth of NMSS/FSME-regulated facilities and activities, no one generic template can be developed. Rather, each analysis must be tailored to suit the particular application being reviewed.

The performance of a value-impact analysis may often require the use of an existing risk assessment. If such an assessment is not available, as is the case in many NMSS/FSME-licensed applications, it must be performed. This assessment can be performed with varying degrees of formality and rigor. It may be a relatively simple, application-specific analysis, or a more detailed facility-risk assessment. The latter may require the assistance of a risk expert. Attempts should be made to include an uncertainty/sensitivity analysis. Such an analysis should include a review of all relevant factors available (assumptions, data, models) that can affect the risk. The number of factors that may affect the risk may be large, and not all may be treated using the same level of detail. However, an effort to identify them is important. When assembled, the factors can be screened to identify the subset to be included in the analysis. This screening process should consider the contribution of each to the risk of the change being analyzed, including the degree of uncertainty associated with each. The reviewers' judgment and experience will be a factor in the screening process. In addition to exposure data, cost measures are also included. Typically, this information (labor rates, interest rates, replacement-equipment costs, etc.) is readily available.

The attributes that may be affected at an NMSS/FSME-licensed facility are shown in Table B-1. Most of these attributes can be analyzed quantitatively in terms of monetary impact, or through radiation exposure, which can be converted to dollars. Others may not be readily quantifiable and may be treated in a more qualitative manner. Efforts should be made, however, to quantify the attributes, if possible. Not every attribute will be pertinent to all value-impact analyses. The data (site-specific or generic) and assumptions used for evaluating each parameter should be documented by the analyst. In the evaluation of each attribute, the analyst should consider uncertainty and should determine the best estimate, as well as minimum and maximum estimates. A summary of the results should be tabulated (Table B-2).

A brief description of each attribute is provided below.

Public Health (Accident): This attribute measures expected changes in radiation exposures to the public because of changes in accident frequency or consequences associated with the proposed action. The appropriate distance from the facility to be analyzed needs to be established on a case-by-case basis. Typically, the effect of the proposed action will be to decrease public exposure (given in person-rems). This decrease multiplied by the monetary conversion factor ($/person-rem) will be given a positive monetary value. It is possible that the

proposed action could increase public exposure from potential accidents. In this case, the increase would assume a negative sign.

Public Health (Routine): This attribute accounts for changes in radiation exposures to the public during normal facility operations (non-accident). Analysis of this attribute will involve actual estimates since accident probabilities are not involved. The product of the decrease in public exposure multiplied by the monetary conversion factor would be taken as positive. An increase in public exposure (multiplied by the monetary conversion factor) would be taken as negative.

Occupational Health (Accident): This attribute measures the health effects (both immediate and long-term) associated with facility workers as a result of changes in accident frequency or accident mitigation. A decrease in worker radiological exposure is taken as a positive, and an increase in worker exposure is considered to be negative.

Occupational Health (Routine): This attribute accounts for radiological exposure to workers during normal facility operations. For many types of proposed actions, there may be an increase in worker exposure. This may be a one-time effect (e.g., installation or modification of equipment in a radiological area), or it may be an ongoing effect (e.g., routine surveillance or maintenance of contaminated equipment). Some actions may involve a one-time increase with an offsetting reduction of future exposure. This attribute represents an actual estimate of health effects; accident probabilities are not relevant. A decrease in worker radiological exposure is taken as a positive, and an increase in worker exposure is considered to be negative.

Offsite Property: This attribute measures the expected total monetary effects on offsite property resulting from the proposed action. Changes to offsite property can take various forms, both direct (e.g., land, food, water) and indirect (e.g., tourism). This attribute is typically the product of the change in accident frequency and the property consequences resulting from the occurrence of an accident (e.g., interdiction cost measures such as decontamination, cleanup, and evacuation). A reduction in offsite property damage is taken as a positive, an increase is considered to be negative.

Onsite Property: This attribute measures the expected monetary effect on onsite property, including decontamination and replacement costs from the proposed action. This attribute is typically the product of the change in accident frequency and the onsite property consequences if an accident were to occur. A reduction in expected onsite property damage is taken as a positive, an increase is considered to be negative. Care should be taken in estimating monetary savings associated with this attribute, since values may be difficult to estimate accurately, and the estimated values may significantly outweigh other values and impacts associated with an alternative.

Industry Implementation: This attribute accounts for the projected net economic effect on the affected licensees to install or implement mandated costs. Costs should include procedural and administrative activities, equipment, labor, and materials. Additional costs above the status quo are considered negative; cost savings would be considered positive. This attribute reflects actual estimated costs; accident probabilities are not involved. This attribute is measured very differently from those associated with accident-related health effects and onsite and offsite property.

Industry Operation: This attribute measures the projected net economic effect from routine and recurring activities required by the proposed action. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive. Costs falling into this category generally occur over long periods of time (facility lifetime) and are sensitive to the discount factor used. Additional costs above the status quo are considered negative; cost savings would be considered positive. This attribute reflects actual estimated costs; accident probabilities are not involved.

NRC Implementation: This attribute measures the projected net economic effect, on NRC, to implement the proposed action. Costs already incurred, including all predecisional activities performed by NRC are viewed as sunk costs and are not to be included. Additional costs above the status quo are taken to be negative; cost savings are positive. NRC may seek compensation (license fees) from the licensees to provide needed services; any compensation received should not be subtracted from the cost to NRC, because NRC is the entity consuming real resources (labor and capital) to meet its responsibilities. Any fees provided by the licensee should be viewed as transfer payments and, as such, are not real costs, from a societal perspective.

NRC Operation: This attribute measures the projected net economic effect on NRC after the proposed action is implemented. Additional inspection, evaluation, or enforcement activities are examples of these costs. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive. As with industry operating costs, NRC operating costs generally occur over long periods of time and are sensitive to the assumed discount factor. If NRC seeks compensation from the licensee for its services, the compensation should not be subtracted.

Other Government: This attribute measures the net economic effect of the proposed action on the Federal government (other than NRC) and State and local governments. Additional costs above the status quo are taken to be negative; cost savings are taken as positive. This attribute will be affected less than many other attributes, but can be relevant in certain types of actions (e.g., changes to offsite emergency planning, provision of offsite services, and new requirements affecting Agreement States). The government entities may seek compensation from the licensee to provide needed services; any compensation received should not be subtracted from the cost to the government units.

General Public: This attribute accounts for direct, out-of-pocket costs paid by members of the public as a result of implementation or operation of the proposed action. Examples could include items such as increased cleaning costs because of dust and construction-related pollutants, property value losses, or other inconveniences. Increases in costs from the status quo are taken to be negative; decreases in costs from the status quo are taken as positive. This attribute is not related to offsite property losses from accidents. The general public attribute measures real costs that will be paid due to the implementation of the proposed action. These costs exclude taxes, as they are transfer payments with no real resource commitment from a societal perspective. Any costs that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

Improvements in Knowledge: This attribute accounts for the potential value of new information, especially from the assessments of the safety of licensee activities. Some NRC actions have as a goal the improvement in the state of knowledge for factors, such as accident probabilities or

consequences, with an ultimate objective of facilitating safety enhancement or reduction in uncertainty. Quantitative measurement of improvements in knowledge depends largely on the type of action being investigated. The value of assessments directed at a fairly narrow issue (e.g., reducing the failure rate of a component) may be quantifiable in terms of safety or monetary equivalent. If this is so, these values and impacts should be treated by the other attributes and not included here. If potential values from the assessments are difficult to identify, or not quantified elsewhere, they should be evaluated with this attribute.

Regulatory Efficiency: This attribute measures regulatory and compliance improvements resulting from the proposed action. These may include changes in industry reporting requirements and NRC's inspection and review efforts. Achieving consistency with international standards groups may also improve regulatory efficiency for both NRC and the industry groups. This attribute is qualitative in nature. However, in some instances, changes in regulatory efficiency may be quantifiable, in which case the improvements should be accounted for under other attributes (NRC implementation or industry operation). Regulatory efficiency actions that are not quantifiable should be addressed under this attribute.

In addition to these attributes, other considerations, including safeguards and security, antitrust, and environmental considerations, may need to be evaluated. For safeguards and security, it must be determined if the existing level of safeguards is adequate and what effect the proposed action has on the level of security. Environmental considerations are typically handled under the National Environmental Policy Act requirements. If not, they must be evaluated but handled separately from the value-impact analysis.

Table B-1. Value-Impact Analysis Generic Template

Attribute	Units	Affected (yes/no)	Change in Accident Frequency	Accident Frequency (per year)	Expected Dose (rem)	Facility Life Cycle (years)	Dose Conversion Factor ($2000/rem)	Interdiction Cost
Public Health (Accident)	$							
Public Health (Routine)	$							
Occupational Health (Accident)	$							
Occupational Health (Routine)	$							
Offsite Property	$							
Onsite Property	$							
Industry Implementation	$							
NRC Implementation	$							
NRC Operation	$							
Other Government	$							
General Public	$							
Improvement in Knowledge	Qualitative							
Regulatory Efficiency	Qualitative							
Antitrust Considerations	Qualitative							
Safeguards and Security Considerations	$							
Environmental Considerations	$							
Other Considerations	$/Qualitative							

Table B-2. Summary of Value-Impact Results Table Template

Quantitative Attribute			Present Value Estimates ($)		
			Low	Best	High
Health	Public	Accident			
		Routine			
	Occupational	Accident			
		Routine			
Property	Offsite				
	Onsite				
Industry	Implementation				
	Operation				
NRC	Implementation				
	Operation				
Other Government					
General Public					
NET VALUE (Sum)					

APPENDIX C

EXAMPLES OF THE APPLICATION OF SCREENING CONSIDERATIONS

APPENDIX C

EXAMPLES OF THE APPLICATION OF SCREENING CONSIDERATIONS

C.1 Introduction

Three examples are provided below to illustrate how the screening considerations may be applied in the materials use and waste arenas. The examples are chosen from three broad areas of regulatory activity. The first example is the in situ leach (ISL) approach for uranium recovery facilities, which represents a broad program area for regulatory consideration. The second example is the License Termination Rule (LTR) for site decommissioning, which represents a change to specific regulation and guidance. The third example is the shipment of the Trojan Reactor Vessel Package, which represents a specific licensing action.

The application of the screening considerations is not only useful in making a decision as to whether to apply RIDM to a particular activity, but also, how to do so (i.e., what information is needed, how it should be organized, and what kinds of issues can, or need to be addressed by applying the RIDM approach).

Note that the screening considerations have been reduced from seven to four as described in Chapter 2. The information provided in this Appendix reports on case studies that used the original seven screening considerations.

C.2 In situ Leach Uranium Recovery Facilities

C.2.1 Background

In the United States, uranium recovery is carried out by conventional uranium mills and by ISL facilities. 10 CFR Part 40 applies broadly to all facilities receiving title to, or receiving, possessing, using, transferring, or delivering, source and byproduct materials, and it has been used for uranium recovery licensing. Criteria for the operation of conventional uranium mills and for the disposition of their tailings and waste are given in 10 CFR Part 40, Appendix A. ISLs developed subsequent to the issuance of Appendix A, and thus certain aspects of the ISL operation, are not covered by this regulation. This includes extraction of uranium from ore beds, certain chemical processes leading up to the conversion of uranium to yellowcake, and the integrity and restoration of the groundwater.

In the absence of specific regulatory criteria for ISLs, the NRC imposes specific “license conditions” on ISL licensees, to protect public health and safety and the environment. It has been recognized that this is not an optimum regulatory framework for ISLs and thus a risk-informed approach has been explored. Accordingly, the NMSS/FSME staff directed its contractor to perform a risk assessment that would address the specific aspects of an ISL, as it relates to health, safety, and the environment. The following illustrates how the screening criteria could have been applied to this broad program area. The discussion below relies heavily on the study performed for the Fuel Cycle Licensing Branch by the CNWRA; namely, NUREG/CR-6733 (Ref. C.1).

C.2.2 Application of Screening Considerations

(1) Could a risk-informed regulatory approach help address the Commission's strategic objective in the NRC's Strategic Plan ?

Although ISLs are new, relative to the conventional uranium mills, it is generally accepted that a comparable level of safety is being achieved. Thus, because this relatively new activity has not been tested by the regulations to the same degree as the conventional mills, risk information could prove to be useful in assessing the level of safety being achieved by ISLs. Secondly, because the framework for the regulation of ISLs is not as complete as for conventional mills, risk information could help to provide insights and guidance for improving the regulatory framework. Thus, risk information would be helpful in maintaining the level of safety and in clarifying the regulatory approach to ensuring that safety is maintained.

It is evident that aspects of the regulatory framework for ISLs can be streamlined through use of risk information. The current approach, using license conditions, is subject to rejection or modification through legal challenges and adds substantial uncertainty. Further, there is no consistent approach to licensing ISLs with a clear focus on the relevant safety issues. Ensuring consistency of requirements across the broad class of ISL licensees is difficult due to the widespread use of license conditions that may differ from site to site.

Because the license condition approach is subject to rejection or modification through legal challenge, it could lead to undue economic and operational impacts for the licensee. It would be important to have a justifiable basis for any changes to the regulations or policy so that regulatory burdens are in proportion to the hazards posed. There is a clear need to focus licensing and inspection policies on the areas that have the maximum impact on safety, while still maintaining overall safety.

Furthermore, the license condition approach does not promote consistent decisions. Each case is handled on its own merits, and these specific decisions would not necessarily promote a clear picture to the public of the level of safety being achieved by the ISL industry. The case-by-case process is not transparent and thus does not enhance confidence. Risk information, especially a risk assessment performed across the broad program area of ISL regulation, would help to communicate important safety information on an integrated and even-handed basis.

Note: NUREG/CR-6733 provides a program-area-wide perspective for the risks from ISL operations and groundwater recovery. As a follow-on, NMSS/FSME is using the risk information and insights gained from this study to promulgate appropriate guidance to the staff for the regulation of ISLs. This study was performed on a generic basis for ISLs and thus provided many of the overarching features of the risk profile for this class of facilities. This can lead to regulatory consistency and effectiveness as the insights from this study are incorporated in the licensing framework. NUREG/CR-6733 also provides insights as to the relative risk at an ISL, including risks posed by both radiological and chemical hazards.

(2) Do data and/or analytical models of sufficient quality exist or could they be reasonably developed to support applying a risk-informed approach to a regulatory activity?

Before the completion of NUREG/CR-6733, there was limited information, in an integrated format, on ISL risks. However, much information was available on a fragmentary basis. For example, inspection reports, environmental impact statements, the NMED database (Ref. C.2), health physics surveys of uranium recovery facilities, guides to chemical hazards, in situ mining studies, and industrial hygiene reports were available to the authors of NUREG/CR-6733. No doubt, it took some effort to acquire this information and even more effort to synthesize it appropriately to produce the risk assessment.

Note: The authors of NUREG/CR-6733 remarked that they did not follow a conventional approach to performing their risk assessment because *"...as the analysis evolved, the authors recognized that for screening purposes, the approach should be tailored to the nature of the specific materials, activities, and regulatory requirements associated with the uranium ISL facilities."* Essentially, they customized their study to the information that was available to them and obtained useful information, on a realistic basis, regarding the risks posed by hazards at ISL facilities.

(3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to NRC, an applicant, or licensee, and/or the public, and provide a net benefit?

To the extent that risk information is recognized to be realistic, it should provide information of value. For ISL facilities, an integrated perspective for risks and safety of the operations that are particular to those facilities was lacking. As discussed above, much of the information in this area already existed in fragmentary form. Thus, elaborate and expensive testing and research programs were not required. The main cost to NRC was in synthesizing this information into a risk assessment. This cost was reasonable, given the fact that an entire class of facilities would benefit.

Note: This type of reasoning probably factored into the decision to carry out the NUREG/CR-6733 study.

(4) Would any other existing factor(s) limit the utility of implementing a risk-informed approach?

In this case, the greatest limitation is probably the ability of the uranium recovery industry to financially participate in new risk-informed activities. Clearly, this is a financially stressed industry, as is evidenced by its unwillingness to embrace the proposed 10 CFR Part 41 development purely for financial reasons. Nevertheless, it is cost-effective for NRC to pursue a risk-informed approach because of the above-mentioned considerations.

Note: Although NMSS/FSME followed up on the risk information developed in NUREG/CR-6733 by developing more generic guidance for licensing and regulatory reviews pertaining to ISLs, a new rule specifically for ISL was not pursued because of the resources required.

C.3 License Termination Rule

C.3.1 Background

Before the issuance of the LTR in 1997 (Ref. C.3), the regulations associated with decommissioning facilities licensed by NRC were derived from the Atomic Energy Act of 1954 and its amendments and pertained to facilities licensed under 10 CFR Parts 30, 40, 50, 60, 61, 70, and 72. In particular, the approach to decommissioning power reactors, as exemplified by Regulatory Guide 1.86, "Termination of Operating Licenses for Nuclear Reactors," June 1974 (Ref. C.4), was a deterministic approach. The criterion for unrestricted release was acceptable surface-contamination levels for a variety of radionuclides including isotopes of uranium, thorium, transuranics, Strontium-90, and various other beta-gamma emitters. Limits of the average, maximum, and removable levels of these radionuclides, in amounts of disintegrations per minute per area (dpm/100 cm^2) were prescribed, and licensees had to demonstrate that all contamination at the site was within these limits. As the complexities of specific site evaluations began to grow, the need for a more effective and efficient approach to decommissioning was given increased consideration. The anticipation of a growing workload in the decommissioning area also contributed to the need for a revision to the regulations.

The LTR approach is based on dose criteria. An acceptable dose level of 25 mrem/yr total effective dose equivalent (TEDE) to the average member of the critical group is defined in the regulations as the criterion for unrestricted release of a reactor site that is undergoing decommissioning. Inasmuch as radiation dose translates directly into a health risk, albeit a small additional risk of latent cancer at these low dose levels, the current regulation can be thought of as incorporating elements of a risk-informed approach in the decision process related to site release. The following discussion demonstrates how application of the screening considerations would have led to this evolution had they been applied before the development of the LTR.

C.3.2 Application of Screening Considerations

(1) Could a risk-informed regulatory approach help address one or more of the goals in the Commission's Strategic Plan ?

Before the LTR, there was a need to ensure that there would be a clear and consistent regulatory basis for determining the extent to which lands and structures must be remediated to ensure safety before decommissioning a site can be considered complete and the license terminated. Here there is a clear need to have a level regulatory playing field across the spectrum of sites and facilities to be regulated.

It was evident that the Commission desired a more efficient and consistent approach to licensing actions related to the numerous and frequently complex anticipated site-remediation activities. Thus, criteria based on dose would lead to a streamlining of the regulatory process.

For some sites, an elaborate and detailed assessment of the residual doses might be warranted. However, for other sites, the residual contamination may be very low. It would, therefore, be useful to have an approach that gives the licensee the option to use a less resource-intensive screening method to demonstrate that an acceptable level of safety had been achieved.

It is helpful to support a decision or relate information on a situation by providing as broad and clear a perspective as possible. Understanding the risks and their trade-offs can only enhance the perspective. It is also important to communicate the benefits as well as the risks of a given situation or decision.

Note: The LTR provides a level playing field. The residual-dose criterion is a performance-based approach that defines adequate safety and does not rely on an evaluation of the complexities of a facility to achieve compliance. In the case of the Trojan application, the NRC review was straightforward. The staff verified that the licensee performed the appropriate analysis to support the goal of unrestricted release. However, Trojan is a site with low levels of residual contamination from licensed operation and the same may not be the case at other sites to be reviewed in the future. A licensee or applicant may want to examine the criteria associated with restricted and unrestricted release and evaluate the risks associated with alternatives on a site-specific basis, to determine the most effective approach, consistent with protecting health, safety, and the environment. In the case of Trojan, the licensee made a business-risk decision by opting to use the screening approach in its License Termination Plan, because the site would likely meet the criteria for unrestricted site release. The LTR approach was developed a few years after the Trojan decommissioning process started. The transparency of the LTR approach, which is a risk-informed approach, seemed to contribute to a stabilization of the interactions with local stakeholders.

(2) Do data and/or analytical models of sufficient quality exist or could they be reasonably developed to support applying a risk-informed approach to a regulatory activity?

Physical models for dose assessment already exist, and they can express parameter uncertainties (referred to in this literature as probabilities). As Ref. C.5 indicates, PA is the overall methodology of choice for performing a decommissioning risk assessment.

Note: Central to the risk-informed approach is the concept of uncertainty. Expressing and understanding uncertainties allows the analyst and decision-maker to assess the risks for the activity in question. There are models for working with uncertainties that have been useful in other contexts, and they should also be useful for assessing the risk related to decommissioning.

(3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to NRC, an applicant, or licensee, and/or the public, and provide a net benefit?

Several models and tools are available and are being refined in the area of dose assessment. There is strong interest in this area, for decommissioning, including international efforts. Much of the investment has been made already. It is now a matter of synthesizing this information into dose (risk) assessments.

Note: Additional refinements of the risk-informed approach may occur for site decommissioning. However, it is not necessary to totally revamp the overall process at once. An evolutionary process is more appropriate and likely to be warranted.

(4) Would any other existing factor(s) limit the utility of implementing a risk-informed approach?

There are no factors that precluded the development of the LTR. On the contrary, it appeared to be an idea whose time had come (on the path to better regulation).

C.4 Trojan Reactor Vessel Package

C.4.1 Background

The Trojan Nuclear Plant in Rainier, Oregon, was permanently shut down in 1993 after approximately 17 years of service. As part of the decommissioning process, Portland General Electric (PGE) removed offsite and disposed of the large components (four steam generators and pressurizer) in 1995. Because of the size (1000 tons) and radiological content (2 million curies) of the reactor vessel, several options were considered:

(1) Ship the reactor vessel, with its internals intact, by barge, up the Columbia River, and transport it over land to the US Ecology site in Richland, Washington;

(2) Store the reactor vessel at the original site of the reactor;

(3) Dispose of the reactor vessel in one piece, with only those internals left inside that were Class C radioactive waste or less; and

(4) Dispose of the reactor vessel and internals separately.

The application submitted to NRC by the licensee, PGE, proposed to transport the vessel by Option 1 and a detailed plan was developed to implement it. The plan included removal of the reactor vessel from its containment, preparation of the vessel with shielding and impact limiters, a special-purpose transporter and barge, and transport routing and timing that reduced specific risks. The transport process was successful. The following discussion demonstrates how application of the screening considerations would have led to the conclusion that a RIDM approach should have been applied to the Trojan Reactor Vessel Package (TRVP) activity.

C.4.2 Application of Screening Considerations

(1) Could a risk-informed regulatory approach help address one or more of the goals in the Commission's Strategic Plan ?

Option 1 could not meet the regulation in 10 CFR Part 71 that requires transport packages to be capable of surviving a 1 meter (3-foot) drop and transport packages to be tested by a 0.3 meter (one-foot) drop onto a flat, unyielding surface. The safety question was: Was an alternative transport equivalent in safety to a transport conforming to the specific regulatory requirement?

PGE devised a special mode of package protection and transport by barge. It submitted a probabilistic safety study for this special transportation by barge, and a probabilistic safety evaluation for the overland shipment. A risk analysis for external events was also included. PGE concluded that it could conduct the transport in a manner that was safer than transport conforming to the prescriptive requirements. The NRC staff reviewed the risk assessments and agreed that the risk was low enough.

This review could be protracted by such considerations as determining the consequences of ramming or sinking, or whether hypothetical one meter (3.3 feet) drops could occur. Resolving such technical issues might have been inefficient and ineffective in reaching a timely resolution. A risk-informed approach to evaluating alternatives would be worthy of exploration.

Currently, a proposal for the revision of 10 CFR Part 71 has been submitted. One of the issues identified in the revision is whether NRC should propose Part 71 amendments to provide a standard for reviewing large-object packages, such as the Trojan Reactor Vessel, versus the current exemption process. As stated in SECY-01-0035, *"...The proposed action would result in enhanced regulatory efficiency by standardizing the requirements to provide greater regulatory certainty and clarity, and would ensure consistent treatment among licensees requesting authorization for special packages"* (Ref. C.6). The current regulations, under Part 71, require an exemption for large-object packages and require Commission approval. The licensee would view the regulatory process as a challenge. In addition, the alternatives to shipment of the vessel, intact, would appear to be substantially more costly, as well as cause higher occupational doses to the workers.

In conclusion, the risk assessment of the alternatives, barge transport versus truck transport, led to an outcome that not only used a risk-informed approach but considerably reduced the regulatory burden on the licensee and the ratepayers in the area.

A risk-informed approach would provide a clear and understandable technical basis for demonstrating that the alternative mode of transport was equally safe. NRC and the licensee could conduct public meetings that would address safety and regulatory concerns involved with the shipment, in which the risk information would show that a wide spectrum of accidents had been considered and accommodated by the design.

In performing the risk assessment, PGE self-identified an elevated risk and made a design change to lower the risk. Risk information benefited communications: the stakeholders in the area readily understood the notion of the relative risk of "one barge vs. 44 trucks." Regulations often prescribe just one way to provide and demonstrate safety, but risk analysis can open the path to many more options, with equivalent or better safety.

(2) Do data and/or analytical models of sufficient quality exist or could they be reasonably developed to support applying a risk-informed approach to a regulatory activity?

The identification of potential accidents would use standard techniques. Risk methods can readily be applied to the problem posed and the options considered. Statistical data on the frequency of various maritime and inland waterway accidents are available from government sources.

(3) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to NRC, an applicant or licensee, and/or the public, and provide a net benefit?

There could be a large potential for savings in this case. These reductions in burden on the applicant and NRC staff would offset the added cost of the risk assessment and associated activities. Potential net benefits are identified below by stakeholder:

Licensee: The shipment of the entire reactor, with its internals, would provide a benefit over the alternative recommendations of indefinite onsite storage and/or segmentation of the reactor vessel package. With the latter, portions of the internals with the highest activation levels would no longer qualify for disposal under 10 CFR Part 61 regulations. It would increase occupational radiation exposure by at least 100% (i.e., 134 to 154 person-rem vs. 67 person-rem). It would result in approximately 44 individual cask shipments to the US Ecology facility. It would increase radiation exposure to the transportation workers by at least 1000% (i.e., 1.06 to 1.19 person-rem vs. 0.09 person-rem). By shipping the reactor vessel as a whole, with internals, the decommissioning schedule would be shortened.

Public: The alternative of segmenting the reactor vessel into 44 individual cask shipments by truck would increase the public exposure to radiation by at least 2300% (i.e., from 0.48 to 0.56 person-rem vs. 0.02 person-rem), although the levels still would have been low. From the modal safety perspective, 44 truck shipments would have had greater risk of a transportation accident than the single barge shipment.

NRC: NRC staff benefits from a relatively clear safety argument for the exemption. NRC also recognized, as a result of this activity, that the regulatory framework may be altered to improve efficiency and effectiveness.

Note: The TRVP transport study brought the benefit-cost of using a risk-informed approach into sharp focus. The risk assessment showed that the alternative action proposed by the licensee, and approved ultimately by NRC, resulted in a significant cost savings. However, this was an unusual outcome, as both risk and cost were decreased by implementing the proposed alternative. It is more usual that a certain amount of risk is decreased at an increased cost, or vice versa.

(4) Would any other factor(s) limit the utility of implementing a risk-informed approach?

There are no precluding factors in this case. Close stakeholder participation can help to assure that there is public acceptance for a course of action.

Note: The exemption was granted and the shipment was made in accordance with all applicable regulatory rules and regulations. According to the response at the public meetings and local newspaper articles, there was no adverse stakeholder opposition to the risk-informed approach taken.

C.5 References

C.1 U.S. Nuclear Regulatory Commission, “A Baseline Risk-Informed Performance-Based Approach for In situ Leach Uranium Extraction Licensees,” NUREG/CR-6733, June 2001.

C.2 U.S. Nuclear Regulatory Commission, “The Nuclear Material Events Database,” http://nmed.inel.gov.

C.3 U.S. Nuclear Regulatory Commission, “Radiological Criteria for License Termination [Final Rule),” *Federal Register*, 62(139), 39058-39092.

C.4 U.S. Nuclear Regulatory Commission, "Termination of Operating Licenses for Nuclear Reactors," Regulatory Guide 1.86, June 1974.

C.5 Eisenberg, N. A., et. al., “Development of a Performance Assessment Capability in Waste Management Programs of the USNRC,” Risk Analysis, Vol. 19, pp. 847-875, 1999.

C.6 U.S. Nuclear Regulatory Commission, “Proposed Rule for Revising 10 CFR Part 71 for Compatibility with IAEA Transportation Safety Standards (TS-R-1), and for Making Other NRC-Initiated Changes,” SECY-01-0035, March 2, 2001.

APPENDIX D

SUPPLEMENTAL INFORMATION ON PERFORMING RISK ASSESSMENTS FOR NMSS/FSME-REGULATED FACILITIES AND APPLICATIONS

APPENDIX D

SUPPLEMENTAL INFORMATION ON PERFORMING RISK ASSESSMENTS FOR NMSS/FSME-REGULATED FACILITIES AND APPLICATIONS

Chapter 3 provided an overview of the four main risk assessment methods that can be used to assess the risk associated with NMSS/FSME -licensed facilities and applications. This Appendix describes some of the common features inherent to these methods.

D.1 The Project Team

One of the most important factors in ensuring a successful risk analysis is the knowledge and experience of the team. Although the exact makeup of the team will be a function of the assessment method chosen and the facility or process to be analyzed, there are some general guidelines that should be followed. Regardless of the assessment method, facility and process experts are needed, since they have the practical understanding of the process (or facility) and how it operates and the problems that may be expected. Other required subject matter specialties may include: human factors, radiation protection, physical and chemical phenomena, environmental protection, and statistics. The latter category is essential in developing reliability estimates and understanding the quantitative results from PRAs.

D.2 Facility/Process Hazard Identification and Screening

This early stage of the risk assessment is a scoping task that consists of defining the objective and outputs needed, then identifying those hazards and types of processes that must be assessed in order to produce that output. Hazards are those materials, objects, or characteristics of the facility that can do harm. By processes is meant those types of chronic conditions or episodic events by which hazards can result in harm. For example, for the hazard of radioactive materials, there are processes of chronic intake or episodic releases. In this scoping task, there are competing goals of technical adequacy and efficiency. Technical adequacy is the need to identify a set of hazards and processes with sufficient completeness so that the resultant output of the assessment can meet its purposes. Efficiency involves screening out some of these hazards and processes, while still obtaining a technically adequate result. For example, if the output of the assessment is to be a risk value that is to be compared to a criterion value, hazards and processes whose total contribution to that risk value can be shown to be negligible relative to the criterion may be screened out. This type of screening inherently involves joint consideration of both consequences and frequency. By using simple bounding assessments, certain hazards and processes can be screened out.

The Preclosure Risk Assessment Methodology (PRAM) (Ref. D.1) was used as a foundation for the discussion on hazard identification and screening for NMSS/FSME -regulated facilities. This methodology described one way to identify and analyze accident scenarios that contributed to the radiological risk associated with the preclosure operation of an HLW geologic repository. However, the approach is sufficiently generic that it can be extended to the broad spectrum of materials and waste applications.

Once all the credible initiating events have been identified, a screening process is used to evaluate the magnitude and nature of the most severe challenges posed by these events. This determination can be made by first assessing the frequency for each event. For NMSS/FSME-regulated facilities, an actual frequency cutoff level should be developed. If used, only events occurring more frequently than this cutoff will need to be considered further. For events occurring with a higher frequency, a boundary hazard assessment is performed. The specific hazards, in terms of radiation dose or chemical consequences to the population at significant risk needs to be identified and assessed for each application. Certain applications, such as medical equipment or gauges, may not need a chemical consequences analysis.

If the risks result in no public, occupational, or environmental releases that exceed risk guidelines, a conclusion can be reached without the expenditure of significant additional resources on the analysis. If, however, the risks are significant, additional evaluation is needed as to the actions, if any, required.

The first step, as discussed in the previous section, is to develop a detailed and structured description of the facility or process. This should include information on processes, operation, and any engineered safety features designed to mitigate or prevent off-normal occurrences. As discussed in previous sections, all hazards, including nonradiological, should be considered. Chemical accidents, although not regulated by NRC, may lead to radiological consequences or the inability of the operator to perform his/her duties. Based on this information, all credible initiating events for the facility or process are identified. The events considered may come from several sources, including an expert panel or a review of available failure and reliability databases (e.g., NMED). The latter would highlight historical initiating events for similar facility groups. The exact method employed to identify the initiating events, as discussed in the previous section, would be dependent on the facility group being analyzed. Generally, for NMSS/FSME licensees, the primary concern would be events that would pose a radiological risk to the workers, the public, or the environment. Based on this, an initiating event would be defined as an event that threatens the integrity of the isolation of the sources of radiation. An initiating event is a deviation from the normal processes, which must be controlled to prevent a direct challenge to the barriers designed to isolate the radioactive materials. An initiator may or may not lead to an off-normal event, depending on the response of the various safety and protection systems available. In addition to initiating events, a radiological risk evaluation must be performed, accounting for occupational, public, and environmental risks. It is also important to consider external events as initiators. Events such as seismic occurrences, floods, and high winds may be initiators, or at the very least, may affect the magnitude of the off-normal events.

The consequence assessment can take many forms, to determine the exact effect on the facility or process. As discussed in the previous section, qualitative and quantitative tools are available. Regardless of the method chosen, there are several key outputs that should result from such an analysis. Once the consequences are identified and analyzed, including specific failures or degradations of any safety systems, the facility can determine what steps must be taken to decrease the probability of occurrence. For many of the NMSS/FSME -regulated facilities, errors by facility personnel are expected to be the leading cause. In these instances, corrective steps may take the form of increased training requirements, revised procedures or processes, or facility modifications. In other groups, such as the long-term storage of radiological waste (both LLW and HLW), environmental consequences may be anticipated because of barrier degradation over a long period of time. For these facilities, improved or additional barriers and monitoring systems may be identified.

If risks can be shown to be bounded by characteristic values, it would suggest that a higher annual frequency cutoff might be acceptable. However, care should be taken to ensure that a regulatory threshold is not violated.

D.3 Delineation of Accident Sequences

This section describes the tasks associated with the delineation of an accident sequence (also referred to as a scenario). These tasks include: (1) identification of accident-initiating events and their screening; (2) construction of potential accident/event sequences that could result in unacceptable consequences; (3) identification and description of controls (i.e., structures, systems, equipment, and components, as well as procedures for normal and off-normal operating conditions) that are relied on to limit or prevent potential accidents or mitigate their consequences; and (4) identification of measures taken to ensure the availability and reliability of identified safety systems. Recognizing the different uses of nuclear material and methods of disposal, and the varying characteristics of the hazards associated with each activity, the extent to which the above tasks are performed depends on the particular hazard targeted in the risk assessment. This section attempts to provide some general guidance for the four categories of the NMSS/FSME -regulated uses of nuclear material and nuclear waste disposal, as grouped in SECY-99-100.

D.3.1 Identification of Initiating Events

The first step in developing a risk model is to define a set of initiating events (IEs). An IE is defined as a physical event or a human error whose occurrence is followed by a sequence of events that may result in either a successful state or a failed state of systems and operator actions leading to an undesirable or unacceptable consequence. The IE identification requires a systematic search across the complete spectrum of activities (both internal and external to the sequence being analyzed for risk) associated with the process for possible energized sources that could lead to unacceptable consequences. For NRC-licensed nuclear material and waste disposal, the unacceptable consequences involve the exposure of workers or members of the public to excessive levels of radiation and hazardous concentrations of certain chemicals, and/or to an adverse impact on the environment. The purpose of identifying IEs is to answer the question “What can go wrong?” in the operation of a facility or a process. The IEs can be categorized as process upsets, management system failures, human errors, and external events (e.g., high winds, floods, and earthquakes).

There is a body of published literature available that provides techniques to identify IEs for the four categories of the NMSS/FSME -regulated uses of nuclear material and waste disposal. For Group 1, which includes HLW and LLW disposal, decommissioning, and mill tailings reclamation, Ref. D.2 provides the technical basis for the PA technique. Detailed guidance for accident scenario analysis is also provided in the paper. To complement the PA, the PRAM document (Ref. D.1) can be a useful tool in providing guidance for selecting and screening the IEs. However, the total risk of low frequency/high consequence events should be considered before screening them out from further analysis.

For Group 2, the regulated activities involve the use of engineered casks to isolate nuclear material under various normal and off-normal conditions. For spent fuel transportation, NUREG/CR-6672 (Ref. D.3) estimates the risks associated with spent fuel shipment via either rail or truck. Risks were estimated for both incident-free transport and transportation accidents. The latter was further divided into severe accidents that result in the release of radioactive materials from the cask to the environment and less severe accidents that cause the cask shielding to be degraded but result in no release of radioactive material. The initiating events for transportation accident scenarios were mainly associated with collision accidents that could result in the failure of the containment seals and lead to the release of radioactive material. These accident scenarios were identified by reviewing past studies of transportation accidents, in particular the Modal Study (Ref. D.4). Other available databases, such as Department of Agriculture (Ref. D.5) and Geographic Information System (Ref. D.6) data were used to quantify the frequency of accident occurrence.

A pilot PRA (Ref. D.7) was recently performed by RES to quantify the risk associated with dry cask storage at a specific reactor site. The three aspects of the dry cask storage operation examined included handling, transfer, and storage. Event trees were established and IE frequencies were quantified. This pilot PRA provides a road map for performing a dry cask PRA, including identification of initiating events. Several external events were also examined, such as aircraft crashes, tornados, flooding, and earthquakes.

Group 3 of the NMSS/FSME -regulated activities encompasses primarily the nuclear fuel cycle facilities and their radiological and chemical hazards. The chemical hazards include hazardous releases resulting from the processing of licensed nuclear material or the potential for chemical hazards to adversely affect radiological safety. One such example is UF_6 vaporization in the fuel fabrication process. For this group of facilities, with multiple sources of hazards, NRC requires an ISA analysis for systematic identification of risks and their quantification. NUREG-1513 (Ref. D.8) provides guidance for performing an ISA; it also provides an example of ISA analysis for a fuel-conversion process. The AIChE (Ref. D.9) is another useful document for information on ISA analysis. Table 1.3 of this reference provides a list of possible IEs, propagating events, risk-reduction factors (controls), and incident outcomes.

Group 4 of the NMSS/FSME -regulated activities involves the use of either sealed or unsealed byproduct material in industrial and medical applications, such as irradiators and radiography. Since many Group 4 applications involve devices that do not require sophisticated hardware systems and components to operate, their risk assessments do not warrant the type of PRA analysis that is most appropriate for understanding a sophisticated process involving complete system configurations. The radiological risk associated with these activities can be assessed using the BHA methods described in NUREG/CR-6642 (Ref. D.10). The BHA assesses both the source hazard and the barriers that confine it. The barriers or controls are considered either as physical hardware or as administrative controls, such as procedures, instructions, and enforcement measures. The BHA identifies deviations from normal operations that could lead to worker or public radiation exposures, along with possible causes, effects, and preventive and mitigative barriers/controls. The question “What can go wrong?” is still valid for identifying the initiating events, such as breach of confinement from a spill, rupture, or mechanical damage; loss of physical control (e.g., a source in an unintended location outside the barrier); and failure of administrative controls.

In addition to the discussions above for the four categories, a recent IAEA report (Ref. D.11) can also be used for the selection and grouping of initiating events. Appendix III of the IAEA report provides a list of typical initiating events for nonreactor nuclear facilities.

D.3.2 Construction of Potential Accident Event Sequences

Regardless what method is chosen for a risk assessment, the next step after IE identification is to construct potential accident sequences. An accident sequence is defined as a specific unplanned sequence of events that could result in an undesirable consequence. Therefore, an important product of the risk assessment is a description of all accident sequences identified and recorded during the analysis process. To identify potential accident sequences, either an inductive or deductive approach can be applied, each having its own advantages. As noted in Ref. D.8, the inductive (bottom-up) approach attempts to identify possible accident sequences by examining deviations from normal operating conditions (e.g., event trees), whereas the deductive approach identifies a top event (usually a severe consequence), and attempts to explain the various ways that the top event can occur (fault tree). Generally, the inductive approaches are useful in identifying a broad range of potential accidents, whereas the deductive approaches provide a deeper understanding of the mechanism by which a particular accident might occur.

The PRA methodology includes logic models, data, physical models, and health and economic-loss models. The logic model identifies those events that are undesirable in the risk arena. Two types of logic trees, an event tree and a fault tree, are used in logic models. Both trees have their foundation in Boolean algebra. The event-tree approach is an inductive method that moves forward in time to delineate events generally through a two-level, logic-type tree: yes/no, fail/success. The fault-tree approach starts with an undesired event (e.g., environmental release) and moves backward in time to determine what led to the event. The PRA method combines both approaches to allow a simultaneous movement forward and backward. The principal advantage of this is that it reduces the number of event combinations that would be present if only one type of approach were used.

Figures D.1 and D.2 provide simplified examples of an event tree and a fault tree, respectively. As shown in Figure D.1, the event tree begins with an initiating event with two separate systems designed to prevent the IE from occurring. Given that the IE occurs, were Systems A and B found in a success state or failure state, and what probabilities are assigned to these branches? In actual situations, this model would be much larger and more involved. If there were N systems, there would be 2^N possible states at the end. When only System A or B is sufficient to perform the overall safety function for the IE, then an event where A is successful, but B fails, will be a safe event. Similarly, the complementary situation (A fails and B is successful) will not be hazardous. As shown in the figure, three events present no hazard, but the failure of both systems will lead to a hypothetical environmental release. The fault-tree models are used when System A comprises subsystems. Going backwards in time using the “and” and “or” gates in the basic logic models, and using Boolean algebra, if both A_1 and A_2 fail, the overall system fails. Again, actual fault trees are larger and more complex. The eventual fault trees are put together and finally quantified through probabilistic expressions.

The development of potential accident sequences requires both a clear understanding of the systems and operating procedures for the subject facility or process, and, as a prerequisite, a team of qualified analysts with training to perform risk analyses. Depending on the facility or process being analyzed, accident sequences could be a full-blown event tree if a PRA or ISA were required (for a process operated with many systems and components), or a simple event tree for a sealed device, using a BHA.

Regardless of the modeling devices chosen, the goal of this task is to develop a logical representation linking the IEs to the corresponding possible end states, with potential consequences. This is accomplished by constructing an event-sequence model that represents the possible combination of safety function and operator responses after the occurrence of each of the initiator groups. An event-sequence model, therefore, describes the sequence of events that, after an IE, leads either to a successful state or to a failed state of systems and operator actions intended to mitigate the consequences.

System failures are logical combinations of simpler events (e.g., component failures). It may be convenient to represent the system response as multiple discrete states, rather than simply binary (success or failure). Also, it may be convenient to include, along with the response of systems and facility operators, phenomenological questions, or "events," in the event-sequence model. An example of the latter might be asking whether an explosive amount of hydrogen could build up in an enclosed space during a certain critical time. The probabilistic answer to such a question might be a function of the uncertainties in the hydrogen generation or release process and depend on the outcome of a previously queried element of the scenario.

As discussed in Chapter 3 and this Appendix, the reference documents for the four groups of the NMSS/FSME -regulated activities can also be used to guide the development of the potential accident sequences. Further, the methods that are popular in the chemical industry, such as HAZOP (Refs. D.12–D.14) may also be employed. As noted in Ref. D.15, tools that can be used include: (1) cause-consequence diagrams; (2) event-sequence diagrams (ESDs); (3) state-space diagrams and Markov analysis; (4) block diagrams; (5) GO charts; and (6) general mathematical simulations of physical systems (e.g., Monte Carlo).

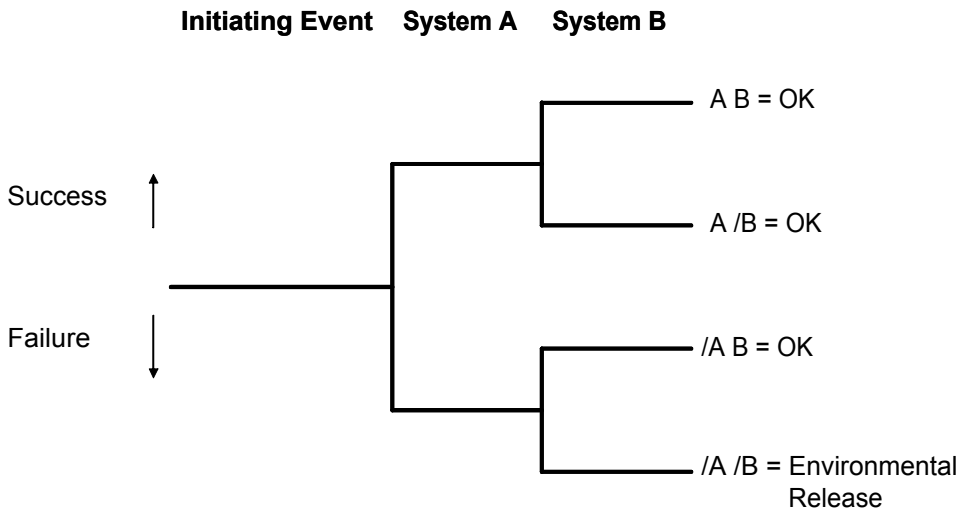

Figure D.1 A Simplified Event Tree

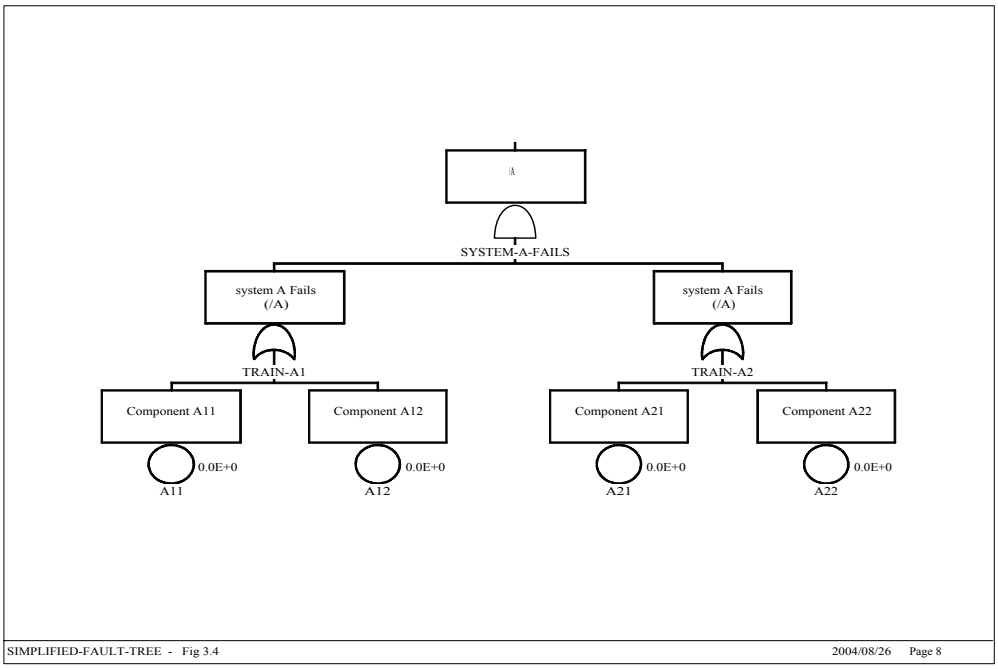

Figure D.2 A Simplified Fault Tree

D.3.3 Identification and Description of Safety Measures, Controls, and Barriers

Once the IEs and accident sequences are established, the safety measures and controls should be identified and described and their reliability should be assessed. The safety measures and safety features are systems or procedures that need to function correctly to prevent or mitigate the occurrence of the accidents that are postulated for each IE. The depth of analysis of safety measures and controls varies, depending on the process and the associated hazard to be addressed. For instance, a medical device may require safety measures pertaining to access control, confinement, and shielding of the source, which can be characterized mainly in terms of procedural controls, rather than in terms of hardware, whereas in a fuel fabrication facility, safety measures may consist of mechanical and electrical systems, emergency power systems, etc., which involve both hardware and procedural safety measures.

Factors to consider in describing the safety measures include whether they have the appropriate sensitivity to detect the need for action after specific IEs, and whether they have a sufficiently rapid response time so that the fault condition arising from the initiator can be corrected before the accident occurs.

It should also be established that the safety measures are capable of functioning correctly under the conditions created by the scenario. This consideration includes the conditions brought about directly as a consequence of the initiator, as well as operational limitations that are a result of additional potential degraded conditions (such as from the independent loss of environmental control, leading to high ambient temperature and humidity).

Clearly, any safety systems that would fail because of the initiator should be identified, and any safety systems so affected should not be claimed in the safety assessment. Likewise, limiting conditions for safety measure effectiveness that might be encountered subsequent to an initiator should be described.

In choosing the safety measures needed to protect against the occurrence of a particular event sequence, both the number and the effectiveness of such measures should be addressed. Similarly, for administrative controls, training measures and audit/inspection measures should be tailored to ensure the specific reliability needed for each control. For example, if the facility is relying on a single individual on duty at a particular time to take action (i.e., close a valve or turn a switch) to avoid a major accident, that person should receive periodic training and his or her performance should be monitored. Another example could be a medical application involving the use of a device with a sealed source. If the device needs to be confined within a set boundary (e.g., operation room), a control measure should be in place to effectively prevent the practitioner from taking the device outside the set boundary.

The relevant information should be obtained from the design specifications for the safety measures, and, for existing facilities, from testing carried out during commissioning and/or as part of a regular examination, inspection, maintenance, and testing program. These bases should be documented in the risk assessment.

In some cases, it may be necessary to consider specific development and testing programs (for non-standard instrumentation, for example). If expert judgment and knowledge are used, it is important to document the bases for the judgment and knowledge.

D.3.4 External Events

The events that are initiated external to the process or facility under consideration are generally grouped in the category usually referred to as external events. The typical external events that could require analysis include seismic events, fires, and high wind. Floods and other external IEs involving accidents related to transportation and events at nearby facilities should also be addressed.

The extent to which the external IEs should be addressed varies, depending on the nature and characteristics of the materials being processed, and systems and components required to mitigate hazards associated with the operation of a particular facility/process. Unlike the NPP, which has a concentrated source of radiation hazard, the NMSS/FSME -regulated activities encompass a wide variety of sources of hazards that employ diverse types of safety measures and barriers. Therefore, for NMSS/FSME facilities, the external events should be addressed on a case-by-case basis for accident prevention and consequence mitigation. For example, seismic events should be addressed for facilities that rely on hardware for production operations and safety measures and controls, such as fuel cycle facilities; however, seismic events may not have much impact on the operation of certain medical applications with sealed sources. On the other hand, waste repositories rely on manmade and natural barriers for safety. For these facilities, the natural phenomena hazards, such as seismic and weather-related events (high winds and floods), can degrade the repository barriers and should be considered and evaluated for decisions involving both site selection and waste emplacement.

Screening for credible external events for a particular NMSS/FSME -regulated facility or process is an important step in determining what external events should be included in a risk model. For those events with very low-occurrence frequencies, a simplified consequence analysis may aid the decision to screen a particular event in or out. Those events being screened in would enter into a risk model for further analysis, whereas the events being screened out because of low consequences would not require further treatment. In either case, the basis for the decision should be documented.

Once an event is screened in, potential accident sequences initiated by that event need to be identified and quantified. The process of sequence identification is much more complicated for external events, especially for seismic events and fires. The risk analysis methodology for seismic events is much more involved, because of the nature of earthquakes and the ground-shaking effects across the board on the structures, systems, and components (SSCs) associated with a facility or a process. A typical analysis for the seismic risk includes a seismic hazard analysis, an initial SSC screen, a seismic-initiated accident sequence analysis, a component fragility analysis, a sequence quantification, and a consequence analysis. Many guidance materials (Refs. D.16–D.20) for a seismic PRA have been published over the years, though mostly directed at NPP facilities. However, the basic elements of these guidance documents should be equally applicable to a seismic-risk analysis for an NMSS/FSME -regulated facility. The task-by-task procedure for a risk analysis of fires includes a fire-hazard analysis, a fire-propagation analysis, a facility and systems analysis, and a release frequency analysis. Two methodologies, FIVE (Ref. D.21) and FPRAIG (Ref. D.22), were developed by the Electric Power Research Institute (EPRI) in response to Supplement 4 to GL 88-20 (Ref. D.23), which called for all commercial NPPs in the U.S. to perform an individual plant examination of external events (IPEEE). FIVE and FPRAIG were the tools provided to NPP

licensees to perform a systematic examination of fires risk. A similar approach can also apply to NMSS/FSME -regulated facilities.

D.4 Facility or Process Systems Analysis

This section discusses the aspects of the risk assessment that require formal consideration and/or detailed analysis in the system evaluation of a facility or process. These include system and process dependencies and a human performance evaluation.

D.4.1 System and Process Dependencies and Interactions

As noted in Ref. D.11, dependent failures can be dominant contributors to the frequency of undesirable end-states and they should be taken into account in the analysis, regardless of the modeling approach selected. In cases where event trees are not used for event-sequence modeling, attention must be paid to the proper handling of the dependencies that appear in the fault trees and to ensuring that they are identified and their logic interrelations are modeled correctly.

The different types of dependencies that can occur include the following:

- Functional and physical dependencies;
- Human interaction dependencies; and
- Component failure dependencies.

Functional dependencies between safety systems, measures, or components can arise when the function of one system or group of components depends on the function of another system or component. These can arise from a number of causes, including the following:

- Shared component;
- Common actuation systems;
- Common isolation requirements; and
- Common support systems (e.g., power, cooling, indication and control, and ventilation).

Functional and physical dependencies share many commonalities. Functional dependencies include physical interaction between systems, measures, or components that can occur when the loss of function of a system or component causes a physical change in the environment of another system or component (e.g. where loss of trace heating on a piece of pipe allows it to freeze in cold weather).

Physical dependencies can arise in two ways. First, an IE can cause the failure of a safety system, measure, or component, as well as the failure of some of the safety systems or components required to provide protection. Secondly, an internal hazard (such as a fire or a flood) or an external hazard (such as extreme environmental conditions or a seismic event) can cause an initiating event and failure of some of the safety systems, measures, or components required to provide protection.

It is important to analyze the interaction between the physical process progression and the performance of the required system or components. To correctly incorporate the effects of physical processes on the accident sequences, the operability of the required systems must be assessed; i.e., the effect of accidental environmental conditions on the engineered safety features and their support systems must be analyzed in detail.

One example of how physical processes may influence the progression of events is the loss of the heating, ventilation, and air conditioning (HVAC) system. Increasing temperature and humidity may affect the functioning of mechanical or electrical equipment, the ability of operators to take appropriate action, and the quality of information provided to the operators.

The equipment within the facility for enabling the operator to perform his tasks is a strong influencing factor. This is particularly true of computer systems. As mentioned, a modern facility may contain more or less sophisticated computer-based operator support systems that monitor the facility performance and display information to the human operator via a man-machine interface (graphic display). The functionality of such systems is determined by the design goals specified during their development.

The ability and appropriateness of such systems to correctly inform the human operator of the different facility states need to be investigated and included in the facility-modeling process. For example, an IE may incapacitate some monitoring functions (the IE may change the temperature of the environment in which a sensor is situated, causing it to become unreliable). As a result, the ability of the operating staff to correctly interpret the information displayed is reduced and this should be reflected in the facility model.

Human interaction dependencies arise when the operators make errors during the repair, maintenance, testing, or calibration tasks that lead to the unavailability or failure of safety systems, measures, or components after an IE. Human interaction dependencies can also arise during the “post-accident” phase, when manual actions require the operator to interact with multiple components.

Component failure dependencies cover those failures of identical components that are otherwise not analyzed. Such failures may be caused by errors in design, manufacturing, installation, calibration, or operational deficiencies and are treated quantitatively by common-cause failure methods or other dependence-quantification approaches. Common-cause failure probabilities are usually quantified by using the alpha-factor approach, the beta-factor approach, the Multiple Greek Letter approach, or the binomial failure-rate model to assess the probabilities of common-cause failures on similar (redundant) components.

D.4.2 Human Performance Analysis

This section highlights the human performance that relates to the IEs and subsequent system responses. Human actions include all those identified, during the course of risk-model development as having potential impacts on the accident sequence structure and results of the model quantification. Human performance analysis usually considers only errors of omission, although some recent developments have been published providing guidance on how errors of commission can be evaluated and modeled.

As discussed in Ref. D.11, the evaluation of human performance depends on the complexity and the degree of automation of the facility or process. Since humans must perform many functions and tasks, accurate evaluation of human performance is crucial for the assessment of risks and their consequences. The depth of human performance analysis is driven by the scope and objectives of a particular risk assessment and influences the selection of analysis methodology. This chapter divides human-performance analysis into two broad categories: qualitative or quantitative.

D.4.2.1 Qualitative Human-Reliability Analysis

A qualitative human-reliability analysis (HRA) is necessary to identify those possible operator actions that, if not properly performed, will have an adverse impact on the development of the accident.

HRA generally involves the evaluation of tasks within a procedure or sequence, while taking into account such factors as the complexity of the task, the conditions under which it is performed, and the mental and physical characteristics and limitations of the operator.

HRA task analysis includes: task decomposition, hierarchical task analysis, time line analysis, task simulation, and ergonomics checklists. Each technique has particular applications, limitations, advantages, and disadvantages. The safety assessor must decide, possibly in consultation with a human-reliability specialist, which techniques should be applied and to what extent.

D.4.2.2 Quantitative HRA

Where the depth of analysis is such that potential human errors are represented in safety-assessment accident sequences (e.g., fault trees or event trees), quantification of human-error probabilities through quantitative HRA is required.

As discussed in Ref. D.11, probability values may be assigned to human errors, using one or more of the following information sources or techniques. In all cases, the individual conditions of the human error under consideration, such as the performance-shaping factors, must be taken into account and the value adjusted as required. Suitably qualified and experienced human-reliability specialists should be consulted if necessary.

Existing Safety Assessments

Where the safety assessor is revising a safety assessment and is able to confirm that there have been no significant changes to the facility's operating procedures and conditions, it may be possible to use the previous safety assessment as a basis for the current one.

Human-Error Databases

It may be possible to select a human-error value by comparing the postulated human errors to ones that have been compiled as part of a database, and for which values have previously been assigned. Extreme care must be taken when using such a database. Justification must be provided that the context and factors influencing human performance are sufficiently similar for the sequence under consideration, when compared to the bases for the actions found in the database.

Derivation of Human-Error Probabilities, using Quantitative HRA Methods

If relevant human-error databases are not available, human-error probabilities can be calculated using various methods published in the literature. There appears to be a consensus on the usefulness and applicability of certain techniques for evaluating human performance, such as those discussed in Ref. D.24, an IAEA report on HRA (Ref. D.25,), and NUREG/CR-2300, "PRA Procedures Guide - A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants" (Ref. D.16), which provides guidance on PRA, including HRA. Examples of specific techniques include: the THERP method (Ref. D.26), SLIM-MAUD (Ref. D.27), ATHEANA (Refs. D.28, D.29), and HEART (Ref. D.30).

As indicated in Ref. D.11, the development of methodologies to represent and understand human performance is continuing on several fronts. In the selection and application of a specific methodology, four guidelines should be taken into consideration:

- The assessment applied to each action evaluated should be consistent.
- All actions should be evaluated within the context of specific event sequences.
- The evaluation should have as a goal that the qualitative ranking of all actions be correct.
- The quantitative evaluation of the actions should be traceable.

Software-Based Quantification Tools

There are some software tools that will calculate a value for a human error. The program requires the input of parameters that could influence the human-error probability, such as the complexity of the operation, the availability of instructions, the degree of training, and the time available to carry out the operation.

D.4.2.3 Human-Interaction Dependencies

As discussed in (Ref. D.11), dependencies between different operators or between different tasks performed by the same operator can significantly affect the overall level of reliability. The human performance analysis should therefore be carefully performed to identify any dependencies between different operators, between different errors committed by the same operator, and even between hardware failures and operator actions (e.g., if operators routinely 'work to' mechanical trips/cut-outs rather than use them as safeguards against operator error). Where dependencies exist, their effects need to be evaluated and quantified. In some cases, this is already accounted for in the individual human-error data, and in other cases, dependencies are accounted for by the effects of performance-shaping factors. Specialist advice should be sought where dependencies are identified that are not accounted for in the human error data. Where specific dependencies cannot be identified, human-performance limiting values are used to limit the claims for human reliability for multiple operator actions. Human-error evaluations implying error likelihoods that are less than 1E-4 require particular justification, whereas evaluations implying error likelihoods that are less than 1E-6 are extremely suspect and most likely should not be used.

D.5 Quantification of Accident Sequences

To quantify the frequencies of the accident sequences, failure rates are assigned to the systems and components involved in the sequences, and frequencies are assigned to each IE. Combining the appropriate system successes and failures with each class of IEs yields a logical representation of each accident sequence. The following sections describe the approaches to accident sequence quantification, general procedures for accident-sequence quantification, and discussion on the computer tools available to assist in the quantification of accident sequences.

D.5.1 Approaches to Accident-Sequence Quantification

As discussed in NUREG/CR-2300, "PRA Procedures Guide - A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants" (Ref. D.16), two distinct approaches have been used in NPPs to quantify the frequency of accident sequences. The fault-tree linking approach consists of combining system and component failures that are not necessarily independent; the event tree with boundary conditions considers combining event-tree tops that are all independent. The first approach automatically takes into account intersystem dependencies within a sequence; the second method involves two steps: 1) the quantification of each independent top event and 2) the multiplication of the probabilities of those top events to get a sequence frequency. The choice of a quantification method depends on the method used to create event/fault-tree models. There is literature available on system quantification techniques, such as the Fault Tree Handbook (Ref. D.31), on techniques to derive reliability parameters (Ref. D.32), and on importance measures (Refs. D.33–-D.35).

D.5.1.1 Fault-Tree Linking

In fault-tree linking, the accident sequence is represented by a fault tree whose top event is connected to “and” gates, with inputs representing the top gates of the system fault trees for each system employed in the accident sequence. Since fault trees are the logic models for combining faults (primary events) within a system or sequence, a set of Boolean expressions can be established that can be further reduced to minimal cut sets, using Boolean algebra. Dependencies among systems or components are thus automatically accounted for in the Boolean reduction process. With this process, the quantification takes place on the overall sequence cut sets, as opposed to the individual systems or components. Furthermore, if multiple sequences are initiated by the same IE, these sequence fault trees can be combined with an “or” gate, to form a single logic model. Since IEs are assumed to be mutually exclusive, the estimated frequencies for sequences with different IEs can then be summed to produce an estimated frequency of the damage state for the facility or process.

The fault-tree linking technique uses “and” gates to model the top events of the event tree, and systems and components and their interdependencies for ensuring success or failure of each top event are logically modeled in the fault tree. The resultant linked fault trees could be large and complex. In these situations, computer codes may be used in spite of the many cut sets that can be generated for quantification.

D.5.1.2 Event Tree with Boundary Conditions

In this approach, system dependencies are explicitly modeled in the event tree. Each system in an event tree is quantified for every set of boundary conditions that has a unique effect on the system-failure probability. The set of boundary conditions consists of a set of components and systems, including dependencies that affect the failure state of the system being quantified. Therefore, the quantification involves the calculation of conditional probabilities, since specific component and system states are assumed. Events are then combined within the event tree by multiplication, to obtain estimated frequencies or approximate frequency distributions for each sequence. The frequencies for sequences initiated from the same initiator are summed up to obtain the frequency for the group.

Because the conditional probabilities are calculated for each top event to explicitly account for the dependency effects, the resultant fault trees for the event-tree top events are thus simpler and independent. In some cases, analyses can be performed by hand without resorting to computer-assisted fault-tree reductions.

D.5.2 General Procedure for Sequence Quantification

Accident sequence analysis begins with the sequence identification, usually followed by grouping similar sequences into damage categories or bins. The damage bins are the groups of sequences that contribute to the same radiological and chemical consequences. The accident sequences that make an insignificant contribution to the total frequency of the bin may be screened out. Once the accident sequences to be quantified have been screened, the quantification can be performed using either fault-tree linking or an event tree with boundary conditions. Both approaches, if rigorously applied, should result in equivalent solutions. However, since in practice, both methods employ approximations and assumptions, the final results for any given solution may vary if the assumptions used are not carefully examined.

For such facilities as fuel enrichment or fabrication, where extensive SSCs are employed in the facility processes, fault-tree linking provides a structure that automatically incorporates interdependencies among the SSCs, can be used to identify common-cause failures and perform the common-cause analysis, and identifies the dominant contributors to the failure frequencies, as well as their rankings. However, implementation of this approach requires considerable effort, usually involving computer programs. For situations where few sequences are identified as associated with the hazard being assessed and where less hardware is involved, (such as use of byproduct materials in certain medical applications), the fault-tree linking would not be a good choice for risk assessment. In these applications, the event trees with boundary conditions can provide a clear and quick insight into the risk associated with a particular sequence. Detailed task-by-task guidance can be found in NUREG/CR-2300, "PRA Procedures Guide - A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants," Section 6.3 (Ref. D.16).

D.5.3 Available Tools for Sequence Quantification

A number of computer codes are currently available for the quantification of event-tree and fault-tree-logic models. Each code is written with particular objectives toward aiding or improving the solution of complex models. However, it is difficult to reach a consensus on any given code, because many different factors may affect the selection of a particular code, such as availability of computer facilities, staff expertise, and the specific objectives of the analysis. Detailed descriptions of various codes can be found in Refs. D.11, D.16, D.36, D.37, and D.38.

D.6 Consequence Analysis

Radiological consequences from direct radiation exposure, inadvertent criticality, and radionuclide release are the impacts on a receptor of the radioactive material (or ionizing radiation) released during an accident, or present in the air, land, or water in and/or near a previously contaminated area. In the case of nonreactor nuclear material facilities, receptors would generally consist of the offsite public, facility workers, and co-located workers. The identification of the population at significant risk is critical in evaluating the risk and is discussed in further detail in Chapter 5 of this document. Note that the consequence analysis is intended to be all inclusive, encompassing transportation of nuclear material, storage packages, and casks, as well as fixed facilities. The radiological impacts are usually evaluated in terms of the following risk metrics: a radiation dose, either an effective dose equivalent, or an organ/pathway specific dose, and an acute or chronic health effect (e.g., early fatality/injury and latent cancer fatality/injury). Some facilities such as uranium-milling operations and enrichment facilities, also use hazardous chemicals. Chemical consequences are estimated in terms of the values of the air concentrations at the location of the potential receptors that are translated into various limits, such as immediately dangerous to life and health (IDLH) values, short-term exposure limit (STEL) values, and emergency response procedure guideline (ERPG) values.

D.6.1 Consequences of Accidents

The estimation of all consequences for accidents should be recognized (e.g., direct radiation, inadvertent criticality, and radionuclide release). Such an estimate may include the following steps:

- Determination of a source term;
- Transport of the release inside and outside the facility (several codes take into consideration the probabilistic simulation of weather conditions for outdoor airborne transport);
- Calculation of the dose rate and exposure time at potential receptor locations inside the facility;
- Calculation of doses and health effects at offsite locations in terms of specified distances and locations from the release point; and
- Estimation of complementary cumulative distribution functions (CCDFs) or exceedance functions for doses and/or health effects.

D.6.1.1 Source Term

The source term is the amount of radiological material released in the accident, the rate of its release, the timing of the release in relation to the initiation of the accident (or the recognition of accident occurrence by the facility personnel), the duration of the release, and the energy of the release. Depending on where the release occurs, various source terms that take into account building ventilation systems and decontamination factors can be defined (e.g., release to the compartment where the accident occurs, release to the facility building, and release to the environment).

Guidance on source terms, including releases, release rates, and related parameters from potential accidents at nonreactor nuclear facilities (including facilities regulated by NRC and the Department of Energy (DOE)) is contained in NUREG-1320 (Ref. D.39) and DOE-HDBK-94 (Ref. D.40).

It is important to note that certain accidents, criticality accidents in particular, involve an end-state that leads to a direct beam of ionizing radiation, such as neutrons and photons, that can directly affect a potential receptor, usually a facility worker, if shielding is missing or inadequate. The analysis of criticality accidents involves estimating the number of fissions in the initial and secondary pulses and the total time and the release fractions of any materials released, such as gases, halogens, and solids. Guidance on methods and codes to calculate the radiation dose from various sources is contained in NRC Regulatory Guides. Shielding codes, such as DORT, MCNP, and SCALE, needed to carry out the calculations, are available from the Radiation Safety Information Computational Center at the Oak Ridge National Laboratory.

D.6.1.2 Transport of the Release

A release is transported from its original location (e.g., a room) to other areas inside the facility building and ultimately to the environment. Transport mechanisms include airborne, groundwater, surface water, and others. The release transport takes into account various barrier and release paths. Transport also involves estimating potential depletion mechanisms inside the building, such as gravitational settling, impaction, thermophoresis, electrophoresis, filtration, tortuosity of the release path. Transport outside the building depends on site-specific weather conditions, such as wind speed and direction, building wake factors, surface roughness of the area over which the release is transported, atmospheric stability factors A - F (if a Gaussian transport model is used to calculate dispersion), and height of the inversion layer. Knowledge of topographical features may be important in some cases where terrain effects have a significant impact on dispersion.

The source term to the building is used to estimate the facility worker dose, depending on receptor location. The source term to the environment is used to calculate the offsite (public) dose or the doses to co-located workers in physically separate buildings at the facility site.

Guidance on in-facility transport models is contained in DOE reports (Refs. D.41, D.42, D.43). Guidance on ex-facility transport models is contained in several NRC and DOE sources. Allowable release rates and concentrations for various pathways are contained in Federal, State, and local regulations. Guidance on meeting these release levels is also available (e.g., regulatory guides). Both probabilistic models (that take into account weather variability over a year or more and perform a Latin Hypercube or a Monte Carlo Sampling to estimate a CCDF of dose vs. distance) and deterministic models are used, depending on the objective of the calculation. The NRC probabilistic consequence assessment code MACCS (Ref. D.44) has been extensively used to calculate the offsite consequences of accidents at NPPs and DOE nonreactor nuclear facilities. Another analytical tool is the RADTRAN code developed by Sandia National Laboratory. RADTRAN combines user-determined demographic, routing, transportation, packaging, and materials data with meteorological data (partly user-determined) and health physics data to calculate expected radiological consequences of incident-free radioactive materials transportation and associated accident risks (Ref. D.45).

D.6.2 Consequences at Decontaminated/Decommissioned Sites

Different methods can be used to estimate consequences when a certain level of contamination is continuously present in the environment. In this case, the objective is to estimate the potential exposure of persons who are resident on, or in the vicinity of, the site. The exposure arises from contaminated soils, groundwater, and, potentially, decommissioned buildings.

Guidance on probabilistic models for estimating doses, such as RESRAD and D&D, is available in NUREG-1757, "Consolidated NMSS Decommissioning Guidance--Characterization, Survey, and Determination of Radiologic Criteria" (Ref. D.46).

D.6.3 Chemical Consequences

Chemical consequences of potential accidents at certain types of NRC-regulated facilities, such as enrichment plants, need to be estimated for both workers and the offsite public. A number of models for performing these calculations have been used within the chemical industry (AIChE) and also at DOE and NRC sites. Many chemical codes include an estimate of the source term and the transport of the release in one package to calculate an air (or a water body) concentration at a specified point assumed to be the receptor location. AIChE publications, Environmental Protection Agency (EPA) documents, and DOE reports contain guidance on the use of particular codes in specific contexts (e.g., heavy-gas dispersion).

D.6.4 Offsite Health Effects

To estimate offsite health effects, all pathways, including inhalation, cloud shine, ground shine, ingestion, and resuspension inhalation, have to be considered. Consequence codes model the exposure based on site-specific population distribution data, farmland, and water bodies at the site, and the counter-measures specified as part of the emergency response. Ingestion doses have to take into account the transport of radionuclides through the food chain and the foods grown or making up the average diet in a particular region. NRC's MACCS code (and the COSYMA code used in Europe) have detailed individual modules for incorporating these factors in the dose calculation.

D.6.5 Onsite Health Effects

Onsite exposure and health effects have to consider the dispersion of released material through the facility and the location of workers, as well as an estimate of the exposure time. The latter will depend on several factors, such as the time taken to evacuate the facility, the recognition of the accident by personnel, the activation of alarms, and the training of the workforce in emergency response procedures.

D.7 Data Analysis

Essential elements of a risk analysis are the collection of data and its assessment with respect to its quality and inherent uncertainties. In contrast to the nuclear power plant arena, where the radiation source is concentrated in the core and the safety systems are designed in the standardized fashion, the NMSS/FSME-regulated activities encompass much broader and diverse industrial and medical applications of nuclear material and waste disposal, where multiple sources of not only radiation hazards but also a variety of chemical hazards, exist. The safety systems and components that are intended to prevent accidents and mitigate their consequences for NMSS/FSME-regulated activities also have diverse features. Therefore, data collection for NMSS/FSME-regulated activities may be much more complex than for NPPs.

However, key methods that were developed from NPP experiences can also be applied to NMSS/FSME-regulated activities for data analysis. One of the general rules applicable to most categories is that data used to characterize or quantify key parameters should be unbiased and estimated as realistically as possible. The use of conservative estimates of the key parameters could lead to unrealistic, overly conservative risk assessments. The elements of data required for risk assessments include: (1) data for sequence frequency estimation; (2) data for assessment of component/system reliability (i.e., fragilities); common-cause failures and initiating event frequency; (3) data required for human performance analysis; and (4) data required for consequence assessments, including source term characterization and the effect of its releases on the public and workers, as well as the environment.

Certainly, plant-specific information should always be investigated thoroughly to collect the data required for a risk analysis. Depending on the situation associated with a particular activity, data that are useful for risk assessment may be scarce. The analysts should be aware of, and encouraged to use, generic databases or other information, but when using such generic information or data for a particular application (i.e., a system), the underlying activities on which the database or information is based should be comparable to those of the system being analyzed.

For initiating event identification, the NMED database (Ref. D.47) may provide numerous real-event records that may be used to derive initiating events. NMED, maintained by the Idaho National Engineering and Environmental Laboratory, is the nuclear material events database that contains records of incidents involving radioactive material licensed under NRC regulations or compatible Agreement States. Reportable events include medical misapplications, loss of materials, malevolent acts (intentional violations), and release of materials. For component failure rate data, the Savannah River database (Ref. D.48) may be consulted. For facilities such as fuel fabrication and enrichment plants, where seismic events may be of concern, the Earthquake Experience and Test Data (Refs. D.49, D.50) may be used for component fragilities. Also as noted in Ref. D.11, examples of analyses are available for treating recovery events within nonreactor risk assessments (Refs. D.51–D.53). Ref. D.11 also provides other references for assessing human-error probabilities and consequences, as well as the data references for release effects on the public.

D.8 Sensitivity, Uncertainty, and Importance Analyses

The reason for adapting the probabilistic approach versus deterministic means for characterizing or quantifying a process or a phenomenon is the probabilistic nature of the universe and the associated uncertainties caused by natural phenomena and a limited human-knowledge base. Therefore, as important parts of a risk assessment, sensitivity analysis, uncertainty analysis, and importance analysis should be performed in conjunction with a baseline risk assessment to gain confidence in, and understanding of, the results. This section discusses these three key analyses and provides some guidance on how they may be performed.

D.8.1 Sensitivity Analysis

The purpose of a sensitivity analysis is twofold: (1) to determine the sensitivity of the calculated risk measures, in terms of either individual doses or cumulative releases of radiation or chemicals, to possible dependencies among system or component failures, and among human errors; and (2) to address those modeling assumptions suspected of having a potentially significant impact on the results. These assumptions are generally in areas where information is lacking and heavy reliance must be placed on the analyst's judgment. Sensitivity analysis can then be accomplished by substituting alternative assumptions for conservatism and evaluating their individual impacts on the results. If significant sensitivities are exhibited with respect to failures of certain dependencies, the risk analysis should describe what conditions, precautions, and actions are in place to help ensure against them; if the risk results are sensitive to data, then the data should be closely scrutinized to ensure the accuracy and adequacy of their underlying representations.

Sensitivity analyses should be performed in three areas: potential component-failure dependencies, potential human performance dependencies, and major assumptions or data employed. For component failure dependencies, the sensitivity analysis is carried out by searching for sensitivity to dependence (hardware coupling), on a system-by-system basis, so that each system can be examined in more depth than would be the case if entire accident sequence cutsets were searched. Whenever the effect of a given dependence failure is substantial, the corresponding impact on the risk results should be assessed, along with a discussion of measures that can be taken to reduce the potential dependence failure or its contribution to the calculated risk.

The human-error-dependence sensitivity analysis should be performed in a manner similar to the component-dependence sensitivity analysis. The suspected dependence cutsets are identified as those containing multiple human errors of any type. Rather than being requantified, these suspected dependence cutsets should be analyzed, and defenses, management controls, or conditions should be established to eliminate the dependencies between human errors in the suspected cutsets.

The sensitivity analysis of assumptions or data employed in the risk assessment can be performed by first searching for suspected conservative assumptions or data that may have important impacts on the risk. Then, alternative assumptions or a different set of data are used and their impact on the risk results is assessed. For example, most seismic PRAs performed for the NRC's IPEEE program used the hazard curves developed by EPRI for the mean CDF estimate, and it was then supplemented with the sensitivity analysis using Lawrence Livermore

National Laboratory's hazard curves (Ref. D.54). After comparing the analyses with the two sets of hazard curves, the majority of the seismic PRAs concluded that the seismic CDF is not sensitive to which hazard curve is chosen, even though one curve may be substantially higher than the other. This is because, in a conventional seismic PRA, the CDF is calculated as the numerical convolution of the conditional-damage-state frequency and the slope of the respective hazard curve. Therefore, as long as the shapes of the hazard curves are similar, the calculated CDF should be similar, regardless of the magnitudes of the curves.

D.8.2 Uncertainty Analysis

Two types of uncertainties should be examined: aleatory uncertainty and epistemic uncertainty. Aleatory uncertainty is associated with physical phenomena that cannot be reduced by model or data improvements. For instance, the uncertainty associated with the thickness of a fuel cask is aleatory because of the allowable tolerance in the manufacturing process. Epistemic uncertainty represents the uncertainty associated with the human understanding of a particular process or physical phenomenon. As the knowledge base increases, our understanding of the physical phenomena is also enhanced, thereby reducing the uncertainty associated with the data and the model. Epistemic uncertainty is reducible as the modeling aspects are refined. In practice, the probability of a sequence may be regarded as representing an aleatory uncertainty and the probability of parameters and models as representing epistemic uncertainties. However, such distinctions are not absolute. For example, in calculating the consequences of disruptive geologic events (fault movement, igneous activity), the timing of such an event may be chosen as a model parameter but clearly it represents an aleatory uncertainty (Ref. D.35).

Sources of uncertainties should be carefully considered to ensure that all uncertainties associated with initiating events, sequence modeling, source-term characterization, and data employed are included, properly characterized, and propagated through the risk model. Some uncertainty is associated with the manner in which the analyst applies the methods and how skillfully or accurately he or she is able to represent the process or system with the adopted modeling method; these uncertainties can be addressed by training the analyst and by using consistent procedures, proper guidance, and review. Modeling uncertainties can also be reduced by making models as realistic as possible, with compensating assumptions and modeling constraints.

Another source of uncertainty is associated with human performance, especially for NMSS/FSME-regulated activities, such as medical and industrial uses of nuclear material. Many accidents involving radiation exposure have been caused by human errors. The uncertainties associated with human errors should be adequately addressed in any risk model. As a minimum, the following sources of uncertainties associated with human performance should be considered (Ref. D.16):

- The dearth of data available on human performance;
- The inexactness of models of human performance that purport to describe how people act in various situations and conditions;
- The identification of all relevant performance-shaping factors and their interactions and effects;
- The skill and knowledge of the human-reliability analyst; and

- The variability in the performance of a given individual and among the performances of different individuals.

The amount of acceptable uncertainty will vary from application to application. For example, a larger degree of uncertainty may be more acceptable for very low-risk applications, where there would be no effect on risk. Instances where the uncertainty has a profound effect on the overall risk need to be examined much more carefully.

D.8.3 Importance Analysis

The purpose of the importance analysis is to identify the important IEs, accident sequences, system failures, and component failures, as well as human errors that are the primary contributors to the underlying risk. The importance measures are usually calculated in a hierarchical fashion, to allow tracing from the important sequence to the system failures to the importance component failures or human errors contributing to the system failure. For a process that involves both active and passive systems, importance measures may require consideration of components that may function either in a binary state or in a continuous fashion, as discussed extensively in Ref. D.35.

Importance measures that have been frequently applied to reactor PRAs include Birnbaum, Fussell-Vesely, Risk Reduction Worth, and Risk Achievement Worth (Refs. D.32, D.33, D.55, D.56). These importance measures calculate either the fractional contribution of the sequence containing the primary event of interest to the total calculated risk or the degradation ratio, which is computed by the conditional-failure probability of a process or system, given the assumed failure of a primary event of interest, divided by the unconditional failure probability of the process or system. However, these importance measures almost always apply to processes or systems that can be modeled, consisting of binary-state components (i.e., either "success" or "failure"). Given the wide variety of NMSS/FSME-regulated activities, it is insufficient to consider only systems whose functionality is modeled as success or failure and whose components are subsystems that are similarly modeled in one of two binary states. Although these tools can be used for certain NMSS/FSME activities, such as fuel fabrication facilities, other NMSS/FSME activities employ not only systems that function in a binary state, but also systems that function in a continuous manner, such as HLW repositories and LLW disposal facilities. A repository relies on both engineered and natural components to prevent the release of radioactivity from the nuclear waste to the environment. Systems relied on to perform such functions act in a passive manner and perform on a continuous scale. Therefore, the determination of a failure state or failure rate for such components is generally meaningless.

Techniques have been developed (Ref. D.35) to measure the importance of a component whose functionality is continuous. These measures were based on risk, in comparison to traditional importance measures, which are based on frequency of failure and are intended to be more suitable to systems comprising components with behaviors mostly easily and naturally represented as continuous rather than binary. It appears that these importance measures can be used to evaluate systems comprising both continuous- and binary-behavior components.

For reactor PRAs, the importance measures are calculated for more than twenty dominant contributors, to ensure a good understanding of the effect of failures of dominant contributing components on the CDF. For NMSS/FSME-regulated activities, the extent to which the importance measures should be used depends on the underlying risk associated with the

particular activity and the number and complexity of the systems and components involved in the particular process or facility. In any event, the effort expended for importance calculations should be commensurate with providing a good understanding of the key systems and components and their contribution to the total calculated risk, so that risk management for the evaluated process or facility can be planned accordingly.

D.9 Documentation of Results

When the analysis is completed, the results must be documented and presented to reviewers and assessors for evaluation and decisionmaking. The documentation should contain the following broad elements:

- Statement of purpose of the analysis (i.e., the regulatory issues being addressed);
- Methodology used to addressed the problem on a technical level;
- Major assumptions being employed in the assessment (e.g., scope and depth of analysis);
- Data being used in the analysis;
- Presentation of results, including an assessment of uncertainties; and
- Conclusions of the analysis relative to the stated purpose of the study.

Specific deliverables should be tailored to the purpose of the study and the obligations of the performers. Various procedural guides (Refs. D.11, D.8, D.16, D.37, and D.57) contain specific suggestions on how to document the particular results of studies.

D.10 Peer Review and Quality of Risk Assessment

Evaluation of the quality of a risk assessment via a process of peer review is an integral component of the risk assessment. Compliance with the intent of guidelines published by NRC or the industry (Refs. D.8, D.16, D.37, D.57) on specific types of analyses may be helpful in streamlining the peer-review process, even though many of the standards and assumptions may not be directly applicable to NMSS/FSME-regulated activities. Currently, a standard for evaluating the quality of a PRA is being developed only for operating power reactors. The importance of PRA quality to the RIDM approach has been recognized by the NRC, and an acceptable and pragmatic means of achieving the requisite PRA quality for regulatory purposes has been proposed (Ref. D.58).

The submittal should document the particular review process used to validate the results, the qualifications of the reviewers, the review findings, and the resolution of contentious issues. Industry risk-comparison studies can be helpful in ensuring that the scope of the risk assessment is appropriate to the risk issues analyzed and that the level of detail and the overall quality of the analysis are adequate. This can entail a comparison of risk assessments between similar facilities and activities. Based on the peer review, the licensee or applicant should justify the technical adequacy of the scope and quality of the risk assessment. This justification and the peer review results should be provided in sufficient detail to allow the NRC staff to perform an independent assessment of the quality of the risk assessment and verification of the results and conclusions offered. Such documentation may also be beneficial in documenting intent in case of adjudication.

D.11 References

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APPENDIX E

SUMMARY OF NMSS/FSME RISK ISSUES AND STATUS OF RISK INFORMATION

APPENDIX E

SUMMARY OF NMSS/FSME RISK ISSUES AND STATUS OF RISK INFORMATION

E.1 Introduction

This appendix contains work carried out in Fiscal Year 2002. Some of the findings may no longer be relevant. The information is provided so that NMSS/FSME Divisions can benefit from the work that has been done.

The scope of NMSS/FSME-regulated areas and applications is broad; it includes ensuring public health and safety through licensing, inspection, and environmental reviews for all NRC activities (except operating power and all nonpower reactors). NMSS/FSME is also responsible for the safeguards technical review of all licensing activities, including the import and export of special nuclear material (excluding reactors).

It has grouped its regulatory responsibilities into four main program areas: (1) fuel cycle safety and safeguards; (2) industrial and medical nuclear safety; (3) spent nuclear fuel storage and radioactive materials transportation; and (4) radioactive waste management. Each area has unique risk areas that have benefited (or could benefit) from risk insights and the application of risk guidelines.

E.2 NMSS/FSME Risk Issues

NMSS/FSME continually uses risk information in providing regulatory oversight. Risk insights have been employed in each of the main program areas, and future risk issues have been identified that could benefit from this application. Each main program area has, to some extent, applied the principles of risk-information. Table E-1 summarizes the potential future applications identified by the Risk Task Group for each area.

Table E-1. Potential NMSS/FSME Program Areas for Applying a Risk-Informed Approach

Program Area	Potential Application
Fuel Cycle Safety and Safeguards - Conversion, Enrichment, and Fuel Fabrication Facilities	**1. Develop a regulatory guide for review of exemption requests that may result in increased risk.** **2. Prepare guidance for performing risk-informed inspections and identifying the risk significance of inspection findings.** **3. Prepare guidance for risk-informed ISA reviews.**

Program Area	Potential Application
Industrial and Medical Nuclear Safety - Use of byproduct, source, or special nuclear material	**1. Develop a vulnerability assessment for materials licensees.** **2. Reevaluate the sealed source and device review process to consider radiological risks for devices.** **3. Reevaluate licensing and device review process for radiography licensees to reflect insights from radiological risk studies.** **4. Revise license renewal process to reflect risk and past performance.**
Radioactive Materials Transportation	**1. Review relative safety and risks associated with compliance with current regulations applicable to handling, storage, transportation, and disposal of spent commercial fuel.** **2. Review and update risk estimates for transportation of radioactive material (other than spent nuclear fuel).** **3. Conduct risk-informed review of licensing and certification process for transport of non-spent fuel radioactive materials and independent spent fuel storage installations ISFSIs).** **4. Develop a risk-informed approach to the inspection process for transportation and spent fuel storage.**
Radioactive Waste Management	**1. Assess relative safety and risks associated with regulatory compliance for handling, storage, transportation, and disposal of spent nuclear fuel.** **2. Develop a generic method for performing risk analyses for dry cask storage facilities.** **3. Develop Total System Performance Assessment Code sensitivity and uncertainty analysis to support risk-informed licensing and inspection.** **4. Incorporate human reliability insights into preclosure safety analysis.** **5. Develop risk-informed licensing and inspections programs for HLW programs.**

E.3 Status of Risk Information

Sources of risk information are available to facilitate the application of a risk-informed approach to NMSS/FSME-regulated activities. For each major NMSS/FSME program area, a list of representative sources of risk-related information is provided. The risk-related references provided are not intended to be all-inclusive. They are, rather, representative references that will provide a foundation for the application of risk information and risk guidelines. The use of these data is not intended to replace actual site-operating data; they are intended to supplement the information and to serve as a basis for those facilities and applications that do not have such data. In addition, other regulatory agencies (i.e., DOE, Environmental Protection Agency (EPA), OSHA) have published reports pertaining to risk that may be applicable to specific aspects of these program areas.

One potential source of applicable data for all NMSS/FSME program areas is NMED, administered by the Division of Industrial and Medical Nuclear Safety, NMSS. It contains data from materials, fuel cycle, and nonpower reactor licensees on events, such as personnel radiation overexposures, medical misadministrations, loss of radioactive material, and potential criticality events.

E.3.1 Fuel Cycle Safety and Safeguards - Conversion, Enrichment, and Fuel Fabrication Facilities

The following references contain examples of risk information applicable to these facilities:

- NUREG/BR-0184: “Regulatory Evaluation Technical Evaluation Handbook” (Appendix D provides risk information related to public health (accident and routine), occupational health (accident and routine) and onsite and offsite property damage for in situ leach mining, milling, conversion, enrichment, fuel fabrication, MOX fuel fabrication and fuel reprocessing facilities).
- NUREG-0706: “Generic Environmental Impact Statement (GEIS) for Uranium Milling”
- NUREG-1531: “Final Environmental Impact Statement for the Atlas Site”
- NUREG-1569: “Standard Review Plan for In situ Leach Uranium Extraction License Applications”
- NUREG-1620: “Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act”
- NUREG-0713: “Occupational Radiation Exposures at Commercial Nuclear Power Plant Reactors and Other Facilities”
- NUREG/CR-6733: “A Baseline Risk-Informed, Performance-Based Approach For In situ Leach Uranium Extraction Licensees”

In addition to these representative NRC-published references, DOE has published data pertaining to risks associated with enrichment plants and handling and storage issues associated with UF_6 containers.

E.3.2 Industrial and Medical Nuclear Safety -- Use of Byproduct, Source, or Special Nuclear Material

The following references contain examples of risk information applicable to these facilities:

- NUREG/BR-0184, “Regulatory Evaluation Technical Evaluation Handbook” [Appendix D includes risk information pertaining to non-fuel cycle facilities (i.e., research, testing, experimental, diagnostic and therapeutic facilities; measurement, calibration, and irradiation facilities; manufacturing and distribution facilities; and service organizations))
- NUREG/CR-6642, “Risk Analysis and Evaluations of Regulatory Options for Nuclear Byproduct Material Systems.”
- NUREG-1717 “Radiological Assessment of Exemptions for Source and Byproduct Materials.”
- NUREG-0713, “Occupational Radiation Exposures at Commercial Nuclear Power Plant Reactors and Other Facilities.”
- NUREG/CR-5392, “Discrete Event Simulation as a Risk Analysis Tool for Remote Afterloading Brachytherapy.”
- NUREG/CR-6088, “Summary of 1991-1992 Misadministration Events.”
- NUREG/CR-5145, “Cellular Investigations of 3M Series 900 Static Eliminators.”
- NUREG-1631, “Source Disconnects Resulting from Radiography Drive Cable Failures.”
- NUREG/BR-0024, “Working Safely in Gamma Radiography.”

E.3.3 Radioactive Materials Transportation

The following references contain examples of risk information applicable to this activity:

- NUREG-0170, “Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Means.”
- NUREG/CR-4829, “Shipping Container Response to Highway and Railroad Accident Conditions.”
- NUREG/CR-6672, “Reexamination of Spent Fuel Shipment Risk Estimates.”
- NUREG-0713, “Occupational Radiation Exposures at Commercial Nuclear Power Plant Reactors and Other Facilities.”
- NUREG/BR-0184, “Regulatory Evaluation Technical Evaluation Handbook” (Appendix D includes risk information pertaining to transportation accidents)
- Generic Letter 96-07,” Interim Guidance on Transportation of Steam Generators.”

In addition to these representative NRC-published references, DOE has published data pertaining to risks associated with enrichment plants and the transportation of UF_6 containers.

Additional risk-informed data may be obtained from NRC licensing documents related to specific facilities. Although facility-specific, this information may be useful in other, similar applications. The following references are typical of the information available:

- Trojan Reactor Vessel SER and Certificate of Compliance
- West Valley TN-BRP and TN-REG Spent Fuel Transportation Casks SER and Certificate of Compliance

E.3.4 Radioactive Waste Management – Hight Level Waste, Low Level Waste, Spent Fuel Storage

The following references contain examples of risk information applicable to these facilities:

- NUREG/BR-0184, “Regulatory Evaluation Technical Evaluation Handbook” (Appendix D includes risk information on spent fuel storage, HLW storage, TRU storage, geological waste disposal, and shallow land disposal)
- NUREG-0713, “Occupational Radiation Exposures at Commercial Nuclear Power Plant Reactors and Other Facilities”
- NUREG-1757,”Consolidated NMSS Decommissioning Guidance”
- NUREG-1573, “A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities”

Additional data may be obtained from NRC licensing documents related to specific facilities. Although facility-specific, such information may be useful in other, similar applications. The following references are typical of the information available:

- Exemption to 10 CFR 72.102F9(f)(1) “Seismic Design Requirements for TMI-2 ISFSI”
- Exemption from 10 CFR 72.212 and 72.214 for the VSC-24 Dry Storage Cask and ISFSI
- PFS, FEIS and SER (contains information on seismic issues, airplane crash hazards, and confinement integrity).

E.4 Need for Additional Risk Information

Significant resources exist for use in applying a risk-informed approach and implementing risk guidelines for NMSS/FSME facilities. These data, when supplemented with other application-specific information, should provide a solid foundation to assist in documenting and reviewing risk-informed submittals and risk guideline applications.

The usefulness of risk-related data increases as new data are obtained and published. Probabilistic risk assessments, ISAs, performance assessments, and barrier/hazard analyses will serve to supplement the existing data and result in increasingly accurate results.

Evidence in the NMSS/FSME materials arena, as well as other nuclear applications, has shown that human reliability plays a significant role in operational safety. Additional data are needed to more accurately model this variable. In addition, some of the data sources are dated (e.g., data from GEIS for the Atlas Mill dates to 1980). Although such historical data are valuable, they

need to be updated with more recent operating and inspection data to reduce inherent uncertainties.

Revised data is also needed in the area of spent fuel behavior during transportation. Use of higher enrichment and higher burn up fuels may need additional characterization studies.

APPENDIX F

(RESERVED)

APPENDIX G

EXAMPLE OF THE USE OF RISK GUIDELINES

APPENDIX G

EXAMPLE OF THE USE OF RISK GUIDELINES

G.1 Introduction

The following example is provided to illustrate how quantitative risk guidelines could be useful in NMSS/FSME activities. This specific example describes how a petition for rulemaking might be handled in a risk-informed manner and addresses the population at risk, implications for internal and external stakeholders, the options for numerical guidelines, and possible decision outcomes.

G.2 Example: Worker Acute Fatality from an Irradiator Accident

The American National Standards Institute submitted a petition for a rulemaking to remove a current regulatory requirement. The petition was for a rule change to remove the requirement for panoramic industrial sterilization irradiators to have a qualified operator physically present onsite, or at the facility, at all times during operations. These irradiators use gamma sources that often total between (2 million) and (5 million) curies for pool-type irradiators. Entry of a worker into the shielded irradiation room during operation would result in a fatal exposure. Such entry is prevented by a number of safety features and practices, one of which is the presence of the trained operator onsite. The request was to have the qualified operator on call but not present onsite at all times. In the case of system malfunctions, the operator would be called to take appropriate action. This is estimated to increase the risk to a non-operator worker who loads products on the continuously operating conveyor leading into the irradiator, since he might attempt to remedy a malfunction in a way that would expose him to a lethal dose. Personnel entry without the qualified operator's knowledge is difficult, and there are automatic protective features. However, unauthorized access is possible for certain designs. Such accidents have, in fact, occurred on several occasions overseas, although not at NRC-regulated facilities.

The use of a risk-informed process to evaluate this proposed rule change would have positive implications for both internal and external stakeholders. For internal stakeholders, use of a RIDM process would provide NRC staff with a consistent, systematic, and defensible way to make risk-management decisions. For external stakeholders, the use of a risk-informed process would provide an objective way to assess a change that would reduce the licensees' burden, as a tradeoff against a small increase in the risk of an accidental acute fatality to workers. The question is whether the increase in risk to workers would be acceptable.

To quantify the change in risk that would occur from a possible rule change, staff conducted a risk assessment. Staff assessed the risk under the current regulatory framework, as well as the change in risk from the proposed rule change. Staff estimated the risk of worker acute fatality per facility to be 5×10^{-8} /yr, under the current regulatory framework. If the operator were not always required to be present, but only on call, as the petition requested, staff estimated the risk as 4×10^{-6} /yr.

Using the draft risk guidelines (QHG4 is the base approach) indicated 4×10^{-6} /yr is no longer less than the 1×10^{-6} /yr limit of the negligible category. Therefore, the estimated individual risk with the removal of the current requirement is not considered negligible. However, with a factor

of 4 greater than QHG 4, the risk is unlikely to be in the unacceptable region. The decision-maker would need to determine whether it is cost-beneficial to grant the exemption. Such a discussion also needs to be balanced by the consideration of security needs, assurance of defense in depth, and maintenance of adequate safety margin.

APPENDIX H

(RESERVED)

APPENDIX I

KEY ISSUES ASSOCIATED WITH THE PROPOSED APPROACH AND IMPLEMENTATION OF GUIDANCE FOR RISK-INFORMED DECISIONMAKING

APPENDIX I

KEY ISSUES ASSOCIATED WITH THE PROPOSED APPROACH AND IMPLEMENTATION OF GUIDANCE FOR RISK-INFORMED DECISIONMAKING

As NMSS/FSME plans to apply the proposed RIDM process and the proposed draft risk guidelines to selected applications in the coming years, certain issues with potential policy implications as well as process implementation become evident. These require further evaluation in order to facilitate a smooth implementation of this proposed process. These issues are organized into two groups: those with potential policy implications and those related to implementation. These issues will be evaluated during the application phase of the proposed systematic RIDM process for NMSS/FSME-regulated activities.

ISSUES WITH POTENTIAL POLICY IMPLICATIONS

(1) Application of the accident risk guidelines for the public to workers

Workers take some voluntary risks in their jobs and are compensated for it. Workers also receive training on radiation protection. For these reasons, the staff has taken the approach that the draft accident risk guidelines for workers can be higher than those for the public. However, since the accident risk guidelines correspond to a level of risk considered to be negligible additional risk, where further reductions may not be warranted, perhaps this level should be the same for workers as for the public. The appropriateness, practicality, and regulatory coherence of such an approach will be evaluated further.

(2) Application of uniform or activity-specific accident risk guidelines for workers

The draft accident risk guidelines for workers are intended for uniform application across all NMSS/FSME-regulated activities. However, it may be more reasonable to adjust these accident guidelines, depending upon the risk in comparable industries, while at the same time retaining the principle of keeping the risk a small fraction of the accident risk in the comparable industries. Also, the risk from routine operations may be a consideration in setting accident risk guidelines. These issues are to be evaluated further.

(3) Application of the accident risk guidelines on an industry-wide or site-specific basis

The calculation of risk for regulated activities, where only small numbers of people are exposed to the risk (such as is the case for many NMSS/FSME-regulated activities), is very sensitive to how this population is identified and modeled. The more people in the population at risk, the less sensitive the calculations are to specific individuals in the model. Accordingly, application of the risk guidelines across an entire industry could result in more realistic average risk estimates but could limit their application to site-specific issues. The advantages and disadvantages of each approach will be assessed during the application phase.

(4) Extent of application of the accident risk guidelines to NMSS/FSME-regulated activities (i.e., is there sufficient guidance available for those regulated activities (e.g., high-level waste and decommissioning) that already rely on quantitative criteria to address accident risk)

Certain NMSS/FSME-regulated activities already have quantitative acceptance criteria that include the consideration of accident risk. It may not be appropriate to apply additional accident risk guidelines to these activities. Accordingly, an evaluation will be made during the application period to determine whether or not certain regulated activities should be excluded.

(5) Consideration of the accident risk from chemical exposure in the scope of the risk guidelines

NRC is responsible for regulating the chemical hazards associated with certain NMSS/FSME-regulated activities (e.g., uranium enrichment). However, risk assessments have not traditionally included chemical risk. The need for, and practicality of, including such a risk in the scope of risk-informed NMSS/FSME-regulated activities will be assessed during the application period.

ISSUES WITH IMPLEMENTATION

(6) Determining the approach for the preliminary draft accident risk guidelines that is best suited for each NMSS/FSME-regulated activity

In response to an Advisory Committee on Nuclear Waste and Materials (ACNW&M) recommendation, the latent cancer QHG values, which are in units of fatalities per year, can be converted into equivalent doses per year by using the ICRP conversion factors of 5×10^{-4} fatalities/rem for the public, and 4×10^{-4} fatalities/rem for workers.

(7) The need for subsidiary accident risk guidelines for some materials or waste activities

The development of reactor safety goals led to establishing two subsidiary objectives; namely, CDF (preventive measure) and LERF (mitigative measure). Subsidiary objectives may be useful because they are easier to use and could provide guidance on measures such as prevention versus mitigation. As it gains more experience from applying a risk-informed approach to NMSS/FSME-regulated activities, the staff may determine the need for developing subsidiary objectives for some activities.

(8) Determining the appropriate population to be considered in estimating the risks and evaluating against the risk guidelines

The staff chose the term “average member of a population at significant risk” for estimating the individual risk associated with the draft risk guidelines. This is analogous to the concept of an average member of a critical group or “reasonable maximally exposed individual,” as recommended by ACNW&M. However, the population at risk varies by regulated activity and is a key factor in the assessment. The appropriate population will need to be defined for each type of activity regulated by NMSS/FSME.

(9) Application of defense in depth in a risk-informed decisionmaking approach

As discussed in the agency's Strategic Plan, defense in depth is an element of NRC's safety philosophy that employs successive compensatory measures to prevent accidents or lessen their effects. Defense in depth ensures that key safety functions are not dependent upon a single element of design, construction, maintenance, or operation. For example, defense in depth can provide for multiple lines of defense, where necessary, to address uncertainties. Preliminary high-level guidance on the application of this philosophy to NMSS/FSME-regulated activities has been included in the draft guidelines and will be tested and further refined in the application period.

(10) Development and application of standards for nonreactor risk assessment quality and documentation

The quality of a risk assessment is a key factor for ensuring sound risk-informed decisionmaking. There is an ongoing effort in RES to develop standards for PRA quality and documentation for reactor applications. The staff will consider the question of what constitutes quality in nonreactor risk assessments (such as ensuring realistic conservatism) after acquiring additional experience with specific risk-informed NMSS/FSME applications, and will determine the need for a standard or standards in this area.

APPENDIX J

APPLYING THE RIDM METHODOLOGY TO FUEL CYCLE FACILITIES

APPENDIX J

APPLYING THE RIDM METHODOLOGY TO FUEL CYCLE FACILITIES

J.1 Review Red Oil Accidents in the Mixed-Oxide Fuel Fabrication Facility

The NRC is in the process of reviewing a license application to construct and operate a facility to manufacture mixed-oxide (MOX) fuel at the U.S. Department of Energy's (DOE's) Savannah River site in South Carolina (Refs. J.1, J.2, J.3 and J.4). The responsibility for ensuring that the facility is designed, constructed, and operated safely resides with the facility operator Duke COGEMA Stone & Webster (DCS). The NRC's role is to provide sufficient oversight and regulation to ensure that public health and safety, the common defense and security, and the environment remain protected.

The NRC is undertaking a review of the processes proposed to be employed at the MOX facility to ensure that the facility is operated within the envelope of the applicable regulations governing safety contained in the Code of Federal Regulations, Title 10 Part 70. Specifically, the NRC staff has been using RIDM methodology to assess the risk of red oil excursions in the MOX facility. The analysis performed by the NRC was based on limited design information available in the MOX fuel fabrication facility (FFF) Construction Authorization Request (CAR) (Ref. J.1). Red oil is defined as a substance of varying composition formed when an organic solution, typically tri-butyl phosphate (TBP) and its diluent, comes in contact with concentrated nitric acid at a temperature above 120 °C. The solvent TBP is often used to extract uranium or plutonium from acid solutions. Even though red oil is relatively stable below 130 °C, it can decompose explosively when its temperature is raised above 130 °C. It is important to analyze the risk from a red oil accident at the MOX FFF because several red oil accidents (Ref. J.5) have occurred in the United States and overseas (for example, at the Hanford Site in 1953, at the Savannah River Site in 1953 and 1975, and at the Tomsk-7 site at Seversk, Russia).

Since the analysis of red oil accident in the MOX FFF was based on limited design information available in the CAR, the analysis included a preliminary risk assessment of certain systems vulnerable to the red oil hazard. The results of this red oil excursion analysis were very helpful to the NRC review staff in focusing attention on items important to safety. Considerably more detail on the design of safety controls is now available in the MOX FFF operating license application. NRC would like to have the red oil analysis updated based on information provided in the operating license application.

J.2 Prioritize Processes and Event Sequences

The MOX FFF applicant has performed an Integrated Safety Analysis (ISA), which attempts to identify all event sequences that could result in high or intermediate consequences, as defined in 10 CFR Part 70.61. The MOX FFF application contains roughly 80 processes, and each process could have a dozen or more event sequences. NRC needs to define a methodology and establish criteria to prioritize the processes and event sequences since there are too many sequences for a detailed risk assessment. The criteria should derive from two primary factors;

1) the likelihood that there is a design deficiency having the particular event sequence and 2) the effect on safety if the deficiency exists. For the first factor, some experience has been compiled in NMSS/Division of Fuel Cycle Safety and Safeguards (FCSS) Interim Staff Guidance (ISG) documents. For the second factor, consideration should be given for how a deficiency could affect subsidiary factors such as individual risk, defense in depth, safety margins and collective risk. An effort is under way to use simplified methods to assess only the higher risk sequences. Examples of simplified methods are available in NMSS/FCSS ISG-01 and NUREG-1718, "Standard Review Plan for the Review of Application for a Mixed Oxide (MOX) Fuel Fabrication Facility." The processes and event sequences would be prioritized to focus on criticality safety and chemical hazards.

J.3 Evaluate Process Hazards Analysis in Integrated Safety Assessment

The first step in an Integrated Safety Analysis (ISA) under 10 CFR Part 70 Subpart H is a Process Hazard Analysis (PHA). The PHA uses systematic techniques to attempt to identify all sequences of potential events in the facility that could lead to high or intermediate consequences (> 5 rem to the public or > 25 rem to a worker). Since the completion of the baseline ISAs by existing fuel cycle facilities in October 2004, events have occurred at these facilities which could have led to high consequences and which had not been identified in the PHA/ISA. These unidentified events are referred to by staff as "unanalyzed events", since they were not identified or analyzed in the ISA.

Since events have occurred at fuel cycle facilities that had not been identified in the PHA, NRC would like to evaluate the effectiveness of the Process Hazard Analysis (PHA) in the ISA and document some insights from previous PHA work. An effort is under way to evaluate the effectiveness of PHA as performed by fuel cycle facility licensees and identify possible deficiencies in licensee PHA processes.

In order to produce lessons learned and general insights that can be applied in future ISA reviews, the staff would seek answers to the following questions:

(1) Why were these events not identified?

(2) Is there a weakness in the methods used by the particular licensees where the events occurred?

(3) Are there other contributing causes?

(4) How great is the concern that other unanalyzed event sequences exist?

(5) What could be done that might improve this situation?

J.4 References

J.1 "Mixed Oxide Fuel Fabrication Facility Construction Authorization Request," Duke Cogema Stone & Webster, in transmittal letters to the U.S. Nuclear Regulatory Commission, October 31, 2002 through February 9, 2005.

J.2 Draft Letter Report, ”Risk-Informed Review of the MOX Facility Licensing Application with Focus on Potential Hazards in the MOX Facility,” Brookhaven National Laboratory, August 2006.

J.3 Draft Letter Report, “Risk Assessment of Red Oil Excursions in the MOX Facility,” Brookhaven National Laboratory, November 2006.

J.4 Letter Report, “Risk-Informed Review of the MOX Facility Licensing Application,” Brookhaven National Laboratory, February 2007.

J.5 U.S. Defense Nuclear Facilities Safety Board, “Control of Red Oil Explosions in Defense Nuclear Facilities,” DNFSB/TECH-33, November 2003.

APPENDIX K

ISSUE CHARACTERIZATION

APPENDIX K

ISSUE CHARACTERIZATION

The purpose of this guidance (Refs. K.1, K.2) is to characterize the issue, in terms of the physical impact on the facility and the potential impact on safe operation, well enough to make an initial assessment of those organizations that must be involved and of the information needed to perform the later steps in the process (e.g., determine which options make sense, decide which technical approaches are appropriate).

The following items should be included in a detailed description of issue:

- Describe the issue.
- Identify how the issue was identified.
- Identify the structures, systems, and components (SSCs) or operational characteristics affected.
- Describe the nature of the effect on the identified SSCs or operational characteristics.
- Identify the safety function(s) affected.
- Identify the plant conditions/ operating environments under which the issue would affect the safety of the plant.
- Identify the regulations (or other requirements/ commitments such as design basis, licensing basis, generic letters) that may be challenged by this issue.
- Assess the expected duration of the issue (when applicable)?
- How long has the issue or condition been present?
- Does it appear that this is/was a temporary condition?
- Is the effect static, or is it likely to worsen with time?
- Identify potential internal (e.g., line and senior management, other divisions or offices, etc.) who may use or be impacted by the risk.
- Identify external stakeholders (other government agencies, industry, affected state and local governments, affected citizens, etc.) who may use or be impacted by the risk.

Additional guidance on Issue Characterization may be obtained from NUREG-BR-0184, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.” (Ref. K.3).

References

K.1 U.S. Nuclear Regulatory Commission, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Regulatory Guide 1.174, Revision 1, November 2002.

K.2 U.S. Nuclear Regulatory Commission, LIC-504, Revision 2, “Integrated Risk-Informed Decisionmaking Process for Emergent Issues,” February 12, 2007.

K.3 U.S. Nuclear Regulatory Commission, NUREG/BR-0184, “Regulatory Evaluation Technical Evaluation Handbook,” January 1997.

APPENDIX L

DEFINING ALTERNATIVE ACTIONS

APPENDIX L

DEFINING ALTERNATIVE ACTIONS

The purpose of this activity is to define the decisionmaking environment, define the alternative actions, describe the decision criteria for acceptance/rejection, describe the factors that determine the analysis approach, and generate a preliminary list of alternative actions/options. To do this, staff should complete the following tasks:

- Define the alternative actions for resolution. These could include, for example, shutting the facility down immediately, shutting it down within a specified time period, continuing operation with the implementation of compensatory actions (for example, continuing operation with increased monitoring), or issuance of an immediately effective order to place or maintain the facility in a safe condition, or delaying the decision until more information is available.
- Describe how the alternative action addresses the regulatory issue.
- Describe what tools, analysis, resources, and costs are needed to implement the alternative action/option.
- Describe the guidelines or criteria for acceptability or rejection of each alternative action. Staff should focus considerations on maintaining defense in depth and safety margins, and minimizing the risk impact.
- Describe the factors that determine the approach to the analysis of the regulatory issue and the selection of actions. A variety of factors, technical and non-technical, can influence this decision. For example, resource limitations, particularly those related to the time available to make a decision, can be an important factor in determining the available options.

NUREG-BR-0184 (Ref. L1) provides additional guidance on how to define alternative actions.

References

L.1 U.S. Nuclear Regulatory Commission, NUREG/BR-0184, “Regulatory Evaluation Technical Evaluation Handbook,” January 1997.

APPENDIX M

INITIAL RISK ASSESSMENT

APPENDIX M

INITIAL RISK ASSESSMENT

After the regulatory issue is characterized, staff should make an initial risk-informed evaluation.

This activity will not only determine and document the significance of the issue, but also provide a base case to facilitate the assessment of various options developed later. Also, much of the information gathered and analytical work performed at this point will be directly applicable to the risk-informed evaluation of each option:

- Is the regulatory issue risk-significant enough that an immediate facility shutdown should be considered?
- Is defense in depth significantly degraded? (e.g., multiple barriers are moderately to significantly degraded; functional redundancy or diversity is significantly compromised; vulnerability to single failures is significantly increased, etc.).
- Is there a significant loss of safety margin?
- Is the issue of low risk? If “yes” then document the finding of low risk.
- Are there other NRC processes for dealing with this issue? If “yes,” initiate the applicable processes.
- Are there generic implications associated with this issue, either already identified or identified as a potential generic issue? Generic implications may trigger other agency processes.
- Which NRC organizations may be affected by or concerned about this issue?

APPENDIX N

ASSESSING THE IMPACT OF THE ISSUE ON DEFENSE IN DEPTH

APPENDIX N

ASSESSING THE IMPACT OF THE ISSUE ON DEFENSE IN DEPTH

It is generally assumed that if the current regulations are met, there is adequate defense in depth at least before the condition/issue arose. However, the analysts should assess the effect of the condition/issue on defense in depth (Refs. N.1, N.2, N.3). The analyst should first consider which of the high level aspects of defense in depth is affected by the issue (for example, barrier integrity, emergency preparedness). The analyst should also assess the effectiveness of compensatory measures (for example, operator actions) to compensate for the degradation of defense in depth. It is important to note that for an event sequence whose outcome is a given level of consequences and a given level of uncertainty in the risk, there should be a minimum level associated with defense in depth or safety margins. Thus, a relaxation of a safety requirement that reduces below the minimum level for defense in depth or safety margins should be rejected.

The following questions are needed to help the analyst to assess the effects of the condition/issue on defense in depth:

Assessment of impact of issue on barrier integrity

Assess impact on barrier integrity (i.e., degradation of the effectiveness of barriers).

- Does the issue significantly change the failure probability of any individual barrier?
- Is the degradation mechanism understood and information (e.g., test or operational data) available regarding the degradation-time relationship for short-term and long-term solutions?
- Is the independence of barriers degraded? If so, which barriers?
- Does the issue introduce new or additional failure dependencies among barriers that significantly increase the likelihood of failure compared to the existing conditions?
- Does the issue result in a significant increase in the existing challenges to the integrity of the barriers?

Assessment of potential for impact on multiple layers of defense in depth

- Are the remaining elements of defense in depth intact? What are they and what is the reason for assuming they are intact?

The intent of this question is to ascertain that the independence of the different layers of defense in depth is not compromised.

Assessment of whether the risk model can address the defense in depth element

- Can the impact of the degradation be quantified and evaluated through the risk model?

Assessment of effectiveness of option in maintaining defense in depth

The analyst needs to consider how a given option changes the defense in depth assessment. The analyst should use the defense in depth guidance above when considering the various alternative actions:

- Does the option propose actions that can compensate for the degradation of defense in depth?
- Discuss the proposed actions. Explain how and to what degree the action(s) can be successful (what level of confidence can be associated with this compensatory measure).
- Does the option identify a programmatic activity that is proposed as a compensatory measure for the identified issue? For example, reliance on operator actions as monitors of plant conditions.
- Describe how the option addresses degradation in defense in depth.
- Identify sources of uncertainty with respect to (1) the assessment of the impact of the degradation of defense in depth, and (2) either the compensatory measures or monitoring approach.
- List assumptions made to address the uncertainties and how they support the option. Assess the confidence level in the option.
- Document why the methods used in the analyses above are considered adequate to support the conclusions.

References

N.1 J.N. Sorensen, G.E. Apostolakis, T.S. Kress, and D.A. Powers, “On the Role of Defense in Depth in Risk-Informed Regulation,” presented at PSA ‘99.

N.2 U.S. Nuclear Regulatory Commission, “Risk-Informed and Performance-Based Regulation”, White Paper, 1999.

N.3 U.S. Nuclear Regulatory Commission, Letter from B.J. Garrick and D.A Powers to R.A Meserve, "Use of Defense in Depth In Risk-Informing NMSS Activities," May 25, 2000.

APPENDIX O

ASSESSING THE IMPACT OF THE ISSUE AND ALTERNATIVE ACTIONS ON SAFETY MARGINS

APPENDIX O

ASSESSING THE IMPACT OF THE ISSUE AND ALTERNATIVE ACTIONS ON SAFETY MARGINS

Margins can be (1) conformance to codes and standards or their alternatives approved for use by the NRC, (2) design margins, (3) safety margins or safety limits, or (4) safety analysis acceptance criteria in the licensing basis. It is important to note that for an event sequence whose outcome is a given level of consequences and a given level of uncertainty in the risk, there should be a minimum level associated with defense in depth or safety margins. Thus, a relaxation of a safety requirement that reduces below the minimum level for defense in depth or safety margins should be rejected.

The following questions are needed to help the analyst to assess the effects of the condition/issue on safety margins:

Assessment of issue on safety margin

- Define “safety margins” relevant to this application.
- What is the basis for the original safety margin and how much conservatism was built in?
- Where was safety margin lost or degraded?
- Identify which aspect of safety margin is compromised and describe the impact. Provide an assessment of the actual extent of loss of safety margin, if measurable or otherwise determinable.
- Document an assessment of the significance of the loss of safety margin, including assumptions made as to the degree of loss, and the expected consequences of functional failure of the affected elements. Document the uncertainty associated with an evaluation of the available margin.

The results of this assessment can be used to guide the uncertainty evaluation for the risk analysis and will provide useful information to help in the overall decisionmaking process. In evaluating safety margins, we can also look at the risk profile of the plant. It would be important for the decision-maker to know if the issue creates or exacerbates a situation where risk is dominated by a few elements (structure, systems and components (SSCs) or operator actions) or a few accident sequences.

- Can the loss of safety margin be quantified in such a way as to provide input to a PRA evaluation?

Assessment of alternative actions on safety margin

The analyst needs to consider how an alternative action changes the safety margins assessment. The analyst should use the following questions to assess the impact of the alternative action on safety margin.

- Describe how the option addresses such degradation in safety margin.
- Are there measures that can be taken to compensate for the potential impact of a loss of margin?
- Describe any compensatory measures and how they address this degradation. Compensatory measures may be proposed by the licensee or by the staff to identify potential options to address the issue. For example, compensatory actions could take the form of monitoring the rate of degradation. Proof of viability would likely require an assessment of the significance of the initial degradation.
- Identify sources of uncertainty with respect to (1) the assessment of the impact of the degradation of safety margin (the base case), and (2) either the compensatory measures or monitoring approach.
- List assumptions made to address the uncertainties and how they support the alternative action. Assess the confidence level in the alternative action.

APPENDIX P

REACHING CONSENSUS ON A RECOMMENDATION

APPENDIX P

REACHING CONSENSUS ON A RECOMMENDATION

This appendix is intended to assist the risk management team in reaching a consensus. In that step, the technical staff involved with the analysis will summarize the results for each decision option. The principal analysts in each discipline (e.g., PRA, engineering, licensing, etc.) will participate in the integration process with other technical staff through a facilitated discussion. The goal of this step is to come to agreement on a recommendation to take forward to decision-makers. This group, the integration team, will work to achieve consensus through the following process:

- Summarize the results of individual assessments and present to the group.
- Led by a team leader chosen for his or her facilitation skills by the lead organization branch chief, discuss the results and evaluations of individual assessments. (The team leader must facilitate the sharing of information and deliberation.) It is critical during this discussion to raise issues, ask questions, and raise and address concerns about risk information, data sources, and other related subjects. The group discussion may identify the need for additional analyses, reframing of the issue, the involvement of additional staff, or other issues.
- With the help of the team leader, decide upon a decision option to recommend to decision-makers. As part of these deliberations, the following questions should be considered for each input to the decision:
  - Do the results of the assessment support the option?
  - Is the appropriate regulatory principle met?
  - What is the basis for this conclusion?
  - Are the analysis tools and supporting data technically adequate?
    - ✓ If the tools are not adequate, describe the inadequacy and potential impacts on the results.
    - ✓ If the supporting data are inadequate, describe the data limitations and potential impacts on the results.
  - Is the conclusion clear and unambiguous?
  - What are the uncertainties that affect this assessment?
  - What confidence do we have in the results/conclusion?
  - What is the significance of the results?
  - In the case that an individual assessment does not support the option, do the results of the other assessments have more weight?
  - How important is this specific assessment to this particular option?

- Attempt to reach consensus on the driving factors or considerations. Consensus is defined as agreement among the integration group members on which decision option is considered "preferred" for taking forward to decision-makers. Given the potentially subjective nature of the risk-informed process, the team may not be able to reach a consensus. If the integration team cannot achieve consensus, options include the following:
  - The dissenters can agree to let the group move on, comparable to abstaining in voting. This minority opinion will be communicated to the decision-maker along with the recommended decision option(s).
  - Iterate back through the process and conduct additional analysis.
  - If the disagreement cannot be reconciled by additional information or analysis, seek management guidance to review the analysis and make a decision based on available analyses.
- Document the results of the assessment as described above.