Attachment 4

Meeting Handouts

a. Agenda
b. Revised screening considerations
c. Copy of case studies poster
d. Draft case studies summary and integration report

Attachment 4a.

Public Meeting to Discuss Use of Risk Information in the Nuclear Materials and Waste Regulatory Process

INTEGRATION OF CASE STUDIES

Thursday, October 25, 2001
U. S. Nuclear Regulatory Commission
Rockville, Maryland

AGENDA

Time	Topic	Presenter
8:00 am - 9:00 am	Poster Session	
9:00 am - 9:10 am	Opening Remarks	L. Kokajko
9:10 am - 9:25 am	Risk-Informing Nuclear Materials and Waste Safety	M. Federline
9:25 am - 11:00 am*	Insights From Case Studies	
	– Overview	M. Bailey
	– Screening Considerations	R. Shane
	– Safety Goals	D. Damon, R. Bari
	– Process Improvements	J. Smith
	– Where We Go From Here	J. Danna
11:00 am - 12:00 noon	Feedback Session	All (facilitated by P. Rathbun)
12:00 noon - 1:30 pm	*Lunch Break*	
1:30 pm - 4:20 pm*	Feedback Session (cont.)	All (facilitated by P. Rathbun)
4:20 pm - 4:30 pm	Closing Remarks	L. Kokajko

*15-minute breaks at around 10:00 am and 3:00 pm.

All Attendees May Participate

Attachment 4b.

Revised Screening Considerations

(1) Could a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?

(2) Could a risk-informed regulatory approach improve the efficiency or the effectiveness of the NRC regulatory process?

(3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?

(4) Would a risk-informed approach help to effectively communicate a regulatory decision?

If the answer to any of the above is yes, proceed to additional consideration; if not, the activity is considered to be screened out.

(5) Do information (data) and/or analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

If the answer to criterion 5 is yes, proceed to additional considerations; if not, the activity is considered to be screened out.

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

If the answer to criterion 6 is yes, proceed to additional consideration; if not, the activity is considered to be screened out.

(7) Do other factors exist which would limit the utility of implementing a risk-informed approach?

If the answer to criterion 7 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or be screened out.

Case Studies – Overview

What are the Case Studies

- Retrospective looks at a spectrum of activities/regulatory decisions in the nuclear materials and waste arenas
- Case studies should illustrate what has been done and what could be done in the materials and waste arenas to alter the regulatory approach in a risk-informed manner
- The intent of the case studies is not to reopen or reassess previous NRC decisions
- The information gained from the case studies may impact future NRC decisions

Objectives of the Case Studies

- Test draft screening criteria/considerations and produce a final version
- Examine feasibility of developing safety goals and, if feasible, develop a first draft
- Gain insights on risk-informing processes
- Identify tools, data and guidance needed

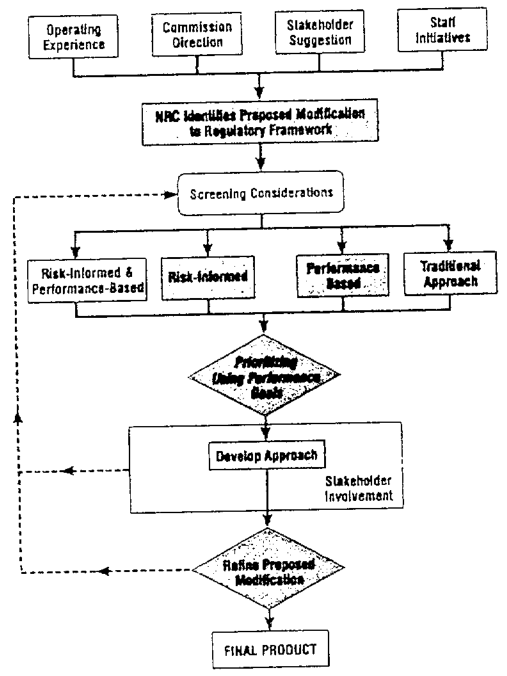
Case Study Areas

- Gas Chromatographs
- Static Eliminators
- Fixed Gauges
- Site Decommissioning (Trojan Nuclear Plant License Termination Plan)
- Transportation (Trojan Reactor Vessel Shipment)
- Uranium Recovery
- Gaseous Diffusion Plant (Paducah GDP Seismic Issues)
- Storage (Seismic Exemption for DOE/INEEL TMI-2 Fuel Debris ISFSI)

What are the Screening Considerations

- Management tool for deciding whether to risk-inform a regulatory area
- Should promote consistency in selecting areas to be risk-informed [redacted]

Application of the Screening Considerations



Screening Considerations

(1) Could a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?

(2) Could a risk-informed regulatory approach improve the efficiency or the effectiveness of the NRC regulatory process?

(3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?

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If the answer to criterion 6 is yes, proceed to additional consideration; if not, the activity is considered to be screened out.

(7) Do other factors exist which would limit the utility of implementing a risk-informed approach?

If the answer to criterion 7 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or be screened out.

Case Study on the Regulation of Gas Chromatographs

Background

Gas chromatographs are used in the industrial and laboratory settings to detect small quantities of organic compounds (1 part in 1014 to 1016). Modified versions of this device known as Chemical Agent Monitors are used by the military to detect poisonous chemical gases in the field. Portable versions are being developed to assist forensic investigators determine time and cause of death.

Reason for Choosing Activity as a Case Study

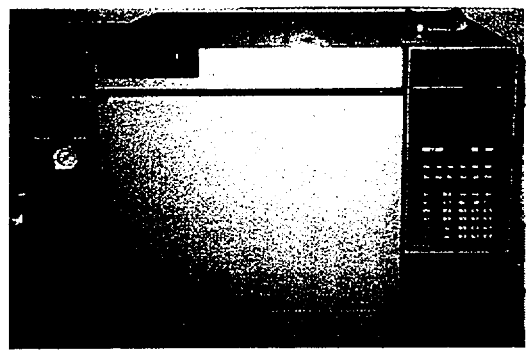
The line between general licenses and specific licenses for almost identical devices appeared inconsistent. A test case for analyzing regulatory framework with regard to risk.

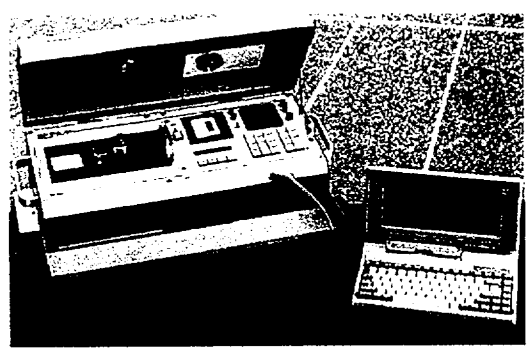
Effectiveness of Screening Criteria

- Passes all of the screening criteria with the possible exception of Question 7. May be useful in future use of risk information in regulatory activities.
- Used as a consideration to be taken by risk managers when determining whether to pursue the use of risk information.

Value of Using Risk Information: Process Improvements

- Indicates that these devices meet or greatly exceed any implicit safety goal.
- The actual risk seems to have little impact on public acceptance.





Implicit/Explicit Safety Goals

- In normal use occupational and public doses should be limited to less than the dose limits in 10 CFR Part 20.
- Possible accident doses in extremely unlikely circumstances must meet the applicable safety criteria in 10 CFR 32.23, 32.24, 32.26, & 32.27

Information, Tools, Methods, Guidance

Sufficient studies have been performed to determine the possible consequences and their probabilities to make a technical decision as to whether regulatory oversight of these devices could be reduced commensurate with their risk.

Case Study on the Regulation of Static Eliminators

Background

Static eliminators are devices that contain a sealed source of radioactive material for the purpose of reducing electric charge buildup on equipment and materials. Static eliminators are used in both consumer and commercial applications under a general license (under 10 CFR 31.3 and 10 CFR 31.5) or a specific license.

Reason for Choosing this Topic as a Case Study

The line between general licenses and specific licenses for almost identical devices appeared inconsistent. A test case for analyzing regulatory framework with regard to risk.

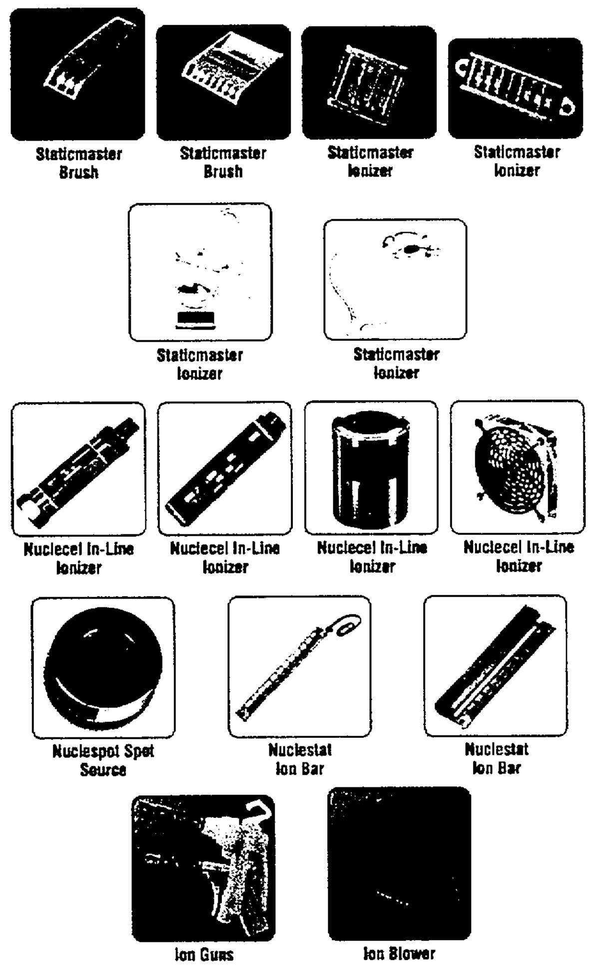
Effectiveness of Screening Criteria

- First four screening criteria demonstrate that increasing the use of risk information in the regulation of static eliminators would support the agency's strategic and performance goals.
- Screening criteria indicate that risk-informing regulation of static eliminators would be technically feasible; however; not clear whether there would be a significant net benefit, in terms of increased efficiency/effectiveness in the regulatory process.

Value of Using Risk Information: Process Improvements

- Risks are evaluated on a case-by-case basis. Efficiency of the regulatory process may be increased by making generalized regulatory decisions based on isotope and activity, or sealed source and device design.
- Integrate device regulation under 10 CFR 31.3 and 10 CFR 31.5; some devices may be made exempt.
- Use risk insights to make the regulation of static eliminators more consistent with other generally licensed, specifically licensed, and exempt devices, from a risk perspective.

Generally Licenced Static Eliminators



Implicit/Explicit Safety Goals

- Protection of the public and workers

  Limit doses to a fraction of the occupational dose criteria in 10 CFR Part 20.

  Prevent direct physical contact with the sealed source within the device.
- Protection of the environment

  Ensure complete containment of the byproduct material (i.e., zero release).

  Ensure complete accountability and control of the static eliminators.

Information, Tools, Methods, Guidance

- Recent risk studies based on Po-210 in laminated foil source. Others isotopes should be evaluated.
- Static eliminators designs specifically licensed, or generally licensed under 10 CFR Part 31.5, undergo an independent safety evaluation prior to approval for distribution.
- Current information regarding the distribution of static eliminators, such as the quantity of each type of device distributed per year, should be compiled to support risk estimates.

Case Study on the Regulation of Fixed Gauges

Background

Fixed gauges are most often used as a way of monitoring a production process or insuring quality control. These devices are used in all types of processing environments, including harsh or hazardous environments. Fixed gauges can be used under a general license or under a specific license, depending, in part, on whether the device meets certain manufacturing and dose criteria in 10 CFR 32.51. Thus, similar devices can be controlled under different regulatory schemes.

Reason for Choosing this Topic as a Case Study

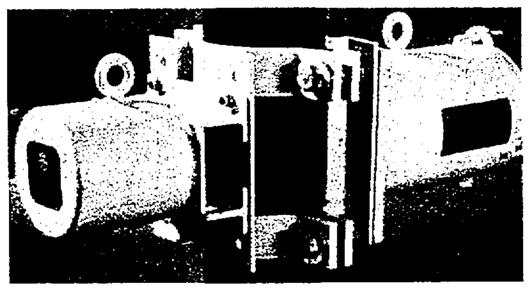
The line between general licenses and specific licenses for almost identical devices appeared inconsistent. A test case for analyzing regulatory framework with regard to risk.

Effectiveness of Screening Criteria

- Provided a path to follow when attempting to make a decision about whether risk-informing is feasible and/or desirable.
- Appeared to contain all the relevant considerations for making risk-informed decisions.

Value of Using Risk Information: Process Improvements

- Provide burden reduction, improve efficiency in decision making and increase regulatory oversight.
- Benefit NRC, licensees, and the public by providing greater controls on devices which are more likely to cause harm.



Implicit/Explicit Safety Goals

- Enable the staff to make decisions which are consistent and defensible.
- The manufacturer's design dose criteria found in 10 CFR 32.51 are elements of safety goals.
- Previous risk-informed staff decisions provide reference points for safety goals on accident risks.

Information, Tools, Methods, Guidance

- Compilation and comparison of previous risk studies should result in a useable source of information to risk-inform the regulation of fixed gauges.
- Inferences may need to be made for the risk-informed regulation of fixed gauges from risk studies for other similar devices.

Case Study on Uranium Recovery

Background

The uranium recovery process primarily consists of the milling and disposal aspects of uranium recovery after the uranium ore is removed from the ground. Waste from milling operations are disposed of in a tailings pile. Mill tailings are fine-grained sand-like waste materials left over from uranium processing. Wastes from in-situ leach facilities may be disposed of in several ways, including release to surface water, evaporated from lined ponds, onsite applications (irrigation) or returned to the aquifers vis deepwell injection.

The NRC does not regulate mining operations (deepwell or surface), and its regulations only apply to the ISL process and subsequent milling processes. NRC efforts for the uranium recovery program are governed by the Uranium Mill Tailings Radiation Control Act of 1978, as amended, and the applicable regulations of 10 CFR Part 40.

Reason for Choosing this Topic as a Case Study

Gaps in the regulations may be found; this may be helpful in testing the screening criteria. The case study could also illustrate how the application of risk information has improved or could improve the uranium recovery regulatory process.

Effectiveness of Screening Criteria

- Revealed chemical is the primary risk, and this risk is not presently regulated by NRC.
- Risk-Informing the regulatory framework could be beneficial, but startup and implementation costs may not be reasonable.

Value of Using Risk Information-Process Improvements

- Risk was used to evaluate various disposal options at a mill site.
- By identifying chemical as a potential risk, operators and regulators can focus resources on this area.
- ISL PRA showed importance of radiological and chemical safety and in maintaining integrity of aquifer against excursions from ore bed

Typical Conventional Uranium Mill

Typical In-Situ Leach Facility Well Field

Implicit/Explicit Safety Goals

- Prevent significant adverse impacts from radioactive waste to the current/future health of the environment.
- Maintain safety and protection of the environment.
- No significant adverse impact on occupational health from UR activities.
- Maintain public confidence in Uranium recovery industry.

Information, Tools, Methods, Guidance

- Sufficient information and tools currently exist (e.g. site specific and generic EISs, ISAs and PRAs; NMED Database, RESRAD, MILDOS-AREA)
- Others may need to be developed.

Case Study on Paducah Gaseous Diffusion Plant Seismic Upgrades

Background

The Paducah Gaseous Diffusion Plant (GDP) is the only operating uranium enrichment plant in the United States. The facility is owned by the United Stated Enrichment Corporation (USEC), which was created by Congress in the 1992 Energy Policy Act. Under this Act, the oversight responsibility for the Paducah GDP is placed on the NRC.

Because of its close proximity to the New Madrid Seismic Zone, seismic safety became an important considerations in the certification of the Paducah GDP. The case study took a retrospective look at the activities undertaken by NRC and USEC to address the seismic issues associated with the plant. The case study examined how, and to what extent, risk information was used to resolve these seismic issues.

Reason for Choosing this Topic as a Case Study

Case study could provide insights on whether the use of risk information could improve the regulatory process for gaseous diffusion plants and establish consistency in applying risk information across materials and waste programs. Also, chemical risks could be explored.

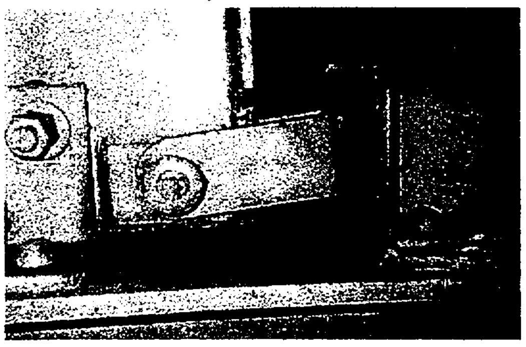
Effectiveness of Screening Criteria

- Clearly showed that risk information was used and was applicable to decision making
- Helped to identify chemical risk as the important contributor
- Helped to identify implicit safety goals

Value of Using Risk Information; Process Improvements

- Established level of risk for particular facility
- Provided basis for Justification for Continuing Operation
- Identified and quantified seismic weak links

Close-Up View of Rocker Arm



Wide View of Rocker Arm

Implicit/Explicit Safety Goals

- No significant impact on public health and safety
- No significant impact on worker health and safety
- No significant impact on the environment

Information, Tools, Methods, Guidance

- Sufficient information and tools currently exist (e.g. risk studies were performed for the certification process, extensions and adaptations of PRA methods, 10 CFR 76)

Case Study on Trojan Nuclear Plant Decommissioning

Background

The Trojan Nuclear Plant operated from 1976 to 1992 and shutdown permanently in 1993. The licensee is now in the process of decommissioning the plant to obtain an unrestricted release of the site. An LTP was prepared to demonstrate that the remainder of decommissioning activities will be performed in accordance with regulatory requirements will not affect public health and safety and the quality of the environment.

Reason for Choosing this Topic as a Case Study

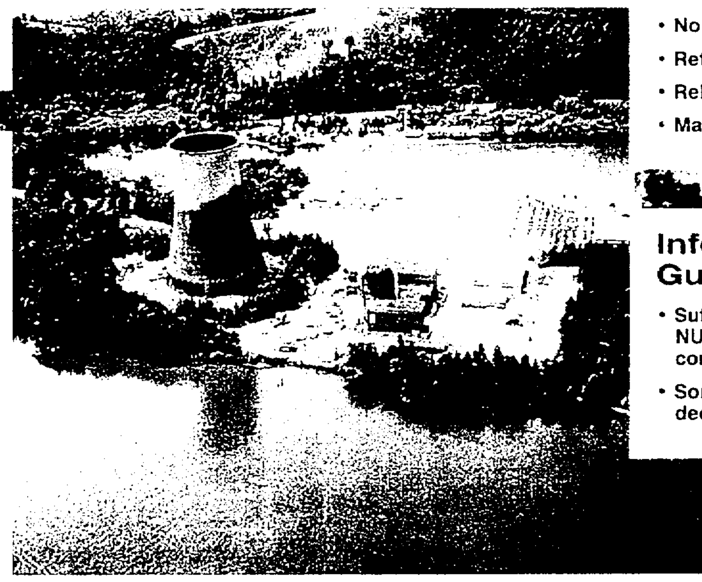
Trojan was the first decommissioning plant to submit an LTP under NRC's new License Termination Rule, which is considered to be risk informed.

Effectiveness of Screening Criteria

- Risk Informed Approach of GEIS/LTR helpful in decision making for evaluating decommissioning options
- Trojan study showed that residual risk levels were extremely low
- Trojan decision to go for screening DCGLs reflected realistic appreciation of site risks

Value of Using Risk Information

- GEIS established value of risk approach to decommissioning
- LTR (Part 20 Subpart E) is risk informed
- Risk informed approach can help in analyzing options for restricted site release



Implicit/Explicit Safety Goals

- No significant additional impact on public/worker health from decommissioning
- No significant additional impact on environment
- Return site to pre-existing conditions
- Release site for unrestricted use
- Maximize number of sites for unrestricted release

Information, Tools, Methods, Guidance

- Sufficient information and tools currently exist (e.g. LTR, NUREG-1727, DCGL Screening Values, DandD, RESRAD cords, MARSSIM, NUREG-1549).
- Some guidance is applicable to other general site decommissioning activities

Case Study on the Transportation of the Trojan Reactor Vessel Package

Background

In 1999, a shipment of an irradiated nuclear reactor vessel, with internals, from the Trojan Nuclear Plant in Rainier, Oregon, was transported to a low level waste disposal site in Richland, Washington. Most of the shipment occurred by barge on the Columbia River.

The probabilistic safety studies provided the basis for the NRC granting an exemption to certain design requirements in 10 CFR Part 71. The exemption allowed the licensee to ship and dispose the Trojan reactor vessel as a whole; thus, reducing radiation risk to workers and saving the licensee and area rate payers millions of dollars.

Reason for Choosing this Topic as a Case Study

Elements of existing, implicit safety goals may be found in Commission decisions; may also be a good case for examining public confidence and communication issues.

Effectiveness of Screening Criteria

- Appeared to contain all the relevant considerations for making decisions as to whether to pursue risk-informing a proposed regulatory action.
- Needed guidance to make their use practical for the staff and clear to stakeholders.
- Would have identified this case as one which would benefit from risk information.

Value of Using Risk Information-Process Improvements

- Showed the potential of risk information to provide for substantial burden reduction and improved staff efficiency at no increase in risk.
- The alternative shipment method that was justified by the risk analysis, was actually a substantial reduction in risk.
- Can open the path to many more options with equivalent or better safety and efficiency.

Implicit/Explicit Safety Goals

- Risk metrics involved in the process of preparing, shipping, and disposing of the reactor vessel, including occupational exposure of workers and accident risks.
- Considered in the decision was the 10^{-6} probability for the most likely accident, a reference point for a safety goal on accidental risks.

Information, Tools, Methods, Guidance

- Resources available for estimating probabilities of transportation accidents. Statistical data exists from several sources.
- Consequences of transport accidents might require quite sophisticated methods, depending on the type of transport package.
- There was no pre-existing guidance saying that 10^{-6} probability would be acceptable. Safety goals are needed to alleviated licensee uncertainty.

Case Study on Seismic Exemption for the DOE/INEEL TMI-2 ISFSI

Background

In 1996, the Department of Energy (DOE) submitted to NRC an application for a license to build and operate an independent spent fuel storage installation (ISFSI) on a DOE site in Eastern Idaho. DOE's decision to transfer the TMI-2 fuel debris from wet storage to dry storage was motivated by concerns that, in the event of a leak, the spent fuel pool water could contaminate the nearby underground water sources. This case study focuses on the exemption to the seismic design criteria specified in 10 CFR Part 72.

Reason for Choosing this Topic as a Case Study

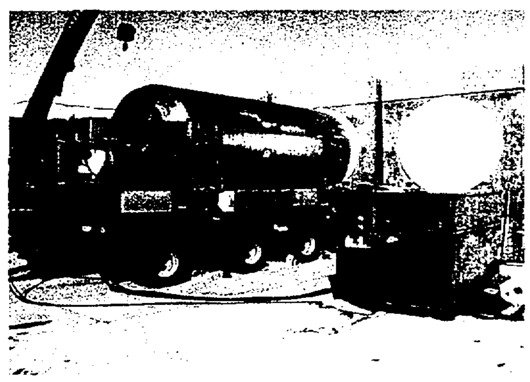
Implicit safety goals may be found in decisions and documents related to the probabilistic hazards analysis exemptions and proposed rulemaking. May also be a good case for examining public confidence issues and burden considerations.

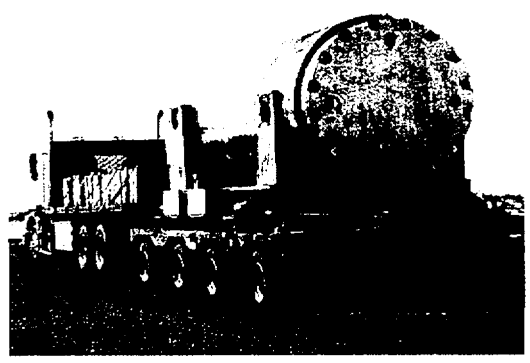
Effectiveness of Screening Criteria

- Appeared to be effective in screening a potential application for risk-informing.
- User should look at the screening criteria in their entirety and make a decision based on all the screening criteria.

Value of Using Risk Information-Process Improvements

- Successfully used to support granting the licensee the seismic exemption in their TMI-2 ISFSI application.
- Highlights the need to revise 10 CFR Part 72 to accept the use of probabilistic seismic hazard analysis method.
- Feasibility in the use of risk in the seismic areas for future ISFSI applications.





Implicit/Explicit Safety Goals

- An implicit safety goal appears to be human exposure to radionuclides should be lower for more frequently occurring events with smaller magnitudes.

Information, Tools, Methods, Guidance

- The risks of dry cask storage were lower than those at an operating nuclear power plant.
- Both deterministic and probabilistic seismic studies have been performed at various locations throughout the proposed ISFSI site. Recent studies (post 1990) were more site specific and included sensitivity analyses.
- Sophisticated probabilistic hazard analysis tools are available to the practitioners but site-specific data is necessary to draw meaningful conclusions.

General Insights from Case Studies

Safety Goals

- Feasible to develop safety goals that cover the wide range of materials and waste applications
- Multi-tiered safety goal structure (like the reactor safety goal structure), with subsidiary objectives for specific applications, is a possible approach
- Decision-making can be facilitated if clear set of safety goals existed

Screening Criteria

- Application can be subjective, guidance needed[redacted]
- Considerations instead of Screening Criteria
- Adequately encompassed the relevant considerations
- Can be a useful decision-making tool

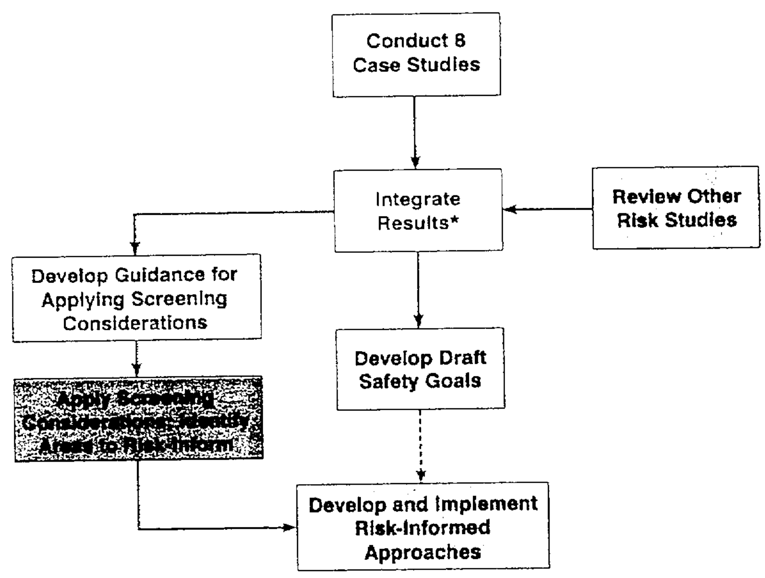
Value of Using Risk Information

- Helped staff to make decisions that were, in retrospect, consistent with Agency's current strategic goals
- Can be useful in identifying shortcomings in our regulations or regulatory processes

Information, Tools, Methods, Guidance

- Mixed; exist in some materials and waste areas, but may need to be developed in others

Proposed Future Actions



* Integrate Results to:
- Finalize screening considerations
- Develop strawman for safety goals
- Identify potential process improvements
- Identify tools, data, guidance needed

Attachment 4d.

Case Studies on Using Risk Information in the Nuclear Material and Waste Arenas:

Summary and Integration Report

DRAFT * * * DRAFT * * * DRAFT

October 9, 2001

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ACKNOWLEDGMENTS

The Risk Task Group, Office of Nuclear Material Safety and Safeguards, wishes to thank the staff of the U.S. Nuclear Regulatory Commission who provided useful information for the case studies, including those staff members who served as subject matter experts for individual case studies: Earl Easton, Yawar Faraz, Michael Layton, Jack Parrott, Drew Persinko, Mahendra Shah, Brian Smith, and Michael Waters. The Risk Task Group also wishes to acknowledge Robert Bari, Vinod Mubayi, Edward Grove and Jimmy Xu, all of Brookhaven National Laboratory, who contributed significantly to completing the set of eight case studies.

1. INTRODUCTION

In Commission Paper SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the staff of the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards (NMSS), proposed a framework for risk-informed regulation in the nuclear materials and waste arenas. The Commission approved the staff's proposal and directed the staff to develop appropriate safety goals for these arenas, and to use an enhanced participatory process that includes regular public meetings with all stakeholders who are involved in or affected by regulation of these arenas.

At the first such meeting, held in April 2000, attendees suggested that screening criteria were needed to identify issues for which risk information would be productive. Attendees further suggested that the development of safety goals and screening criteria would be enhanced by studying actual regulatory cases in the materials and waste arenas, to see how risk information was, or could have been, used.

The NMSS staff adopted this suggestion and, as part of the overall risk-informing effort, has been conducting case studies of a spectrum of activities in the nuclear materials and waste arenas. The NMSS staff is currently consolidating and integrating the results of the individual case studies to further the following objectives:

(1) Produce final screening criteria for the materials and waste arenas.

(2) Illustrate how the application of risk information has improved or could improve particular areas of the regulatory process in the materials and waste arenas.

(3) Determine the feasibility of safety goals in the particular areas studied. If feasible, develop safety goal parameters and a first draft of safety goals. Otherwise, document the reasons why this is infeasible.

(4) Identify methods, data, and guidance needed to implement a risk-informed regulatory approach.

It is not an objective of the case studies to reconsider the regulatory actions that the NRC took in the case being studied. The objectives are strictly those listed above.

The NMSS has been conducting all of its case studies using a standardized approach, described in the "Plan for Using Risk Information in the Materials and Waste Arenas" (October 2000, ADAMS Accession ML010040111). The case studies are largely retrospective; that is, they involve regulatory and physical actions that the NRC has already taken. Each case has been studied by a member of the NMSS Risk Task Group or a contractor with risk expertise. Advisors include subject matter experts from the NRC staff who have knowledge of the particular case. The reviewers have also consulted with licensees and other stakeholders having knowledge of the particular case, through a series of public workshops.

The basis for each case study has been the review of information from NRC and licensee source documentation, through which the staff answers a standardized list of

questions that address aspects of the four objectives listed above. After the investigative phase of the study, the NMSS staff generated a set of preliminary conclusions on the basis of the answers to these questions. The staff then presented its preliminary conclusions at a public workshops in which all stakeholders were invited to participate. After incorporating information and ideas that emerged from these meeting, the NMSS staff produced reports documenting each case study.

This draft summary report is the first step towards consolidating and integrating the results of the case studies. It is based on the information the NMSS staff has provided in the most recent drafts of the final case study reports. NMSS staff will make available and discuss the final case studies reports at a public workshop at NRC Headquarters in Rockville, Maryland, on October 25, 2001.

In addition to this section (Section 1), this draft case study integration report has two other section. Section 2 provides summaries and highlights the key points for each of the eight case studies. Section 3 provides identifies insights that may be gleaned from comparing and contrasting the case studies. The NMSS staff will discuss these insights at the public workshop on October 25, 2001.

2. CASE STUDY SUMMARIES AND KEY POINTS

This section presents brief summaries of the eight case studies. Each case study summary includes key points related to the four overall case-study objectives identified in Section 1:

- Effectiveness of the draft screening criteria
- The value of using risk information in the regulatory activity/area and potential process improvements
- Identification of explicit or implicit safety goals
- Availability of methods, data, tools, and guidance

The final report for each case study discusses the key points in detail.

2.1 Case Study on the Regulation of Gas Chromatographs

Gas chromatographs are used in the industrial and laboratory settings to detect small quantities of organic compounds (1 part in 1014 to 1016). Modified versions of this device known as Chemical Agent Monitors are used by the military to detect poisonous chemical gases in the field. Portable versions are being developed to assist forensic investigators determine time and cause of death.

Gas Chromatographs are regulated by NRC under the requirements specified in 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

Reason for Choosing this Topic as a Case Study

The line between general licenses and specific licenses for almost identical devices is unclear. The case study could illustrate how the application of risk information could improve a particular area of the regulatory process.

Key Points

Effectiveness of Screening Criteria

- The application passes all of the screening criteria with the possible exception of Question 7. The screening criteria may be useful in the future in deciding whether to use risk information in regulatory activities; however, questions related to public acceptance of the use of this information can only be guessed a priori.

- These criteria should be used as a consideration to be taken by risk managers when determining whether to pursue the use of risk information in making regulatory decisions on a case by case basis.

Value of Using Risk Information: Process Improvements

- This case study of Gas Chromatographs indicates that these devices meet or greatly exceed any implicit safety goal, and are likely to also meet or exceed any reasonable explicit quantitative or qualitative safety goal that may be developed in the future.

- The actual risk, consequence times the probability, seems to have little impact on public acceptance.

Implicit/Explicit Safety Goals

- In normal use occupational and public doses should be limited to less than the dose limits in 10 CFR Part 20.

- Possible accident doses in extremely unlikely circumstances must meet the applicable safety criteria in 10 CFR 32.23, 32.24, 32.26, & 32.27

Information, Tools, Methods, Guidance

- Sufficient studies have been performed to determine the possible consequences and their probabilities to make a technical decision as to whether regulatory oversight of these devices could be reduced commensurate with their risk.

2.2 Case Study on the Regulation of Static Eliminators

Static eliminators are devices that contain a sealed source of radioactive material for the purpose of reducing electric charge buildup on equipment and materials. The radiation from the radioactive source produces ions in air, which neutralize the static charges in their vicinity. As a consumer product, static eliminators may be used to reduce static charges on photographic film and lenses, and the static charges that can hinder the delicate operation of balances of precision. Commercial applications for static eliminators include the following: (1) to reduce the risk of fire or explosion due to static charge buildup and discharge in volatile and explosive environments (e.g., paint shops), (2) to reduce the buildup of static charges that can damage electronic circuits and hard drives during assembly and repair of personal computers, (3) to reduce the buildup of dust on surfaces to be electroplated or painted, and (4) to reduce the static cling of processed material on sheet-fed webs and rollers (e.g., print shops).

Consumer and commercial use of static eliminators is regulated under by NRC under the requirements specified in 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 31, "General Domestic Licenses for Byproduct Material."

Reason for Choosing this Topic as a Case Study

This may be good case for examining risk communications and public confidence issues.

Key Points

Effectiveness of Screening Criteria

- The first four draft screening criteria focused consideration on whether increasing the use of risk insights in the regulation of static eliminators would support one or more of the Agency's four performance goals in the Materials Safety Arena.

- The last three draft screening criteria focused consideration on whether there were any technical, policy, economic, or other issues that would prevent, or minimize the benefits of, increasing the use of risk insights in the regulation of static eliminators.

Value of Using Risk Information: Process Improvements

- Case study indicated that the risks associated with individual models of static eliminators are evaluated on a case-by-case basis. The may be potential for increasing the efficiency of the regulatory process by making more general regulatory decisions based on isotope and activity, or sealed source and device design. Also, the regulation under 10 CFR 31.3 may be better integrated with the static eliminator regulation under 10 CFR 31.5.

- Risk insights may be used to make the regulation of static eliminators more consistent with other generally licensed, specifically licensed, and exempt devices, from a risk perspective, thus increasing regulatory effectiveness and efficiency and reducing unnecessary regulatory burden, while maintaining health and safety.

Implicit/Explicit Safety Goals

- The isotope and activity should be limited to meet the occupational dose criteria in 10 CFR Part 20.

- The sealed source design should ensure complete containment of the byproduct material (i.e., zero release).

- The static eliminator design should prevent direct physical contact with the sealed source within the device.

- Administrative requirements should ensure complete accountability and control of the static eliminators.

Information, Tools, Methods, Guidance

- Several early studies of risks associated with static eliminators were based on a sealed source design (i.e., microspheres) that is no longer being used; however, the more recent studies are based on the current sealed source design, which is a laminated foil.

- The recent risk studies consider only polonium-210 as a source; however, other isotopes are being used as the source in generally licensed and specifically licensed static eliminators.
- Each static eliminator design that is specifically licensed, or generally licensed under 10 CFR Part 31.5, undergoes an independent safety evaluation by the responsible regulatory agency prior to approval for distribution.
- Current information regarding the distribution of static eliminators, such as the quantity of each type of device distributed per year, should be compiled to support risk estimates.

2.3 Case Study on the Regulation of Fixed Gauges

Fixed gauges are most often used as a way of monitoring a production process or insuring quality control. These devices are used in all types of processing environments, including harsh or hazardous environments. The types of fixed gauges regulated by NRC are primarily thickness gauges, density gauges, level gauges, insertion gauges, and volumetric flow gauges that contain gamma or beta radiation sources. The most common radioactive materials used in fixed gamma gauges are cobalt-60, cesium-137, and americium-241. In fixed beta gauges, the most commonly used radioactive materials are krypton-85, strontium-90, promethium-147, and thallium-204.

Use of fixed gauges is regulated by NRC under the requirements specified in 10 CFR Part 20, "Standards for Protection Against Radiation," 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." Fixed gauges can be used under a general license or under a specific license, depending, in part, on whether the device meets certain manufacturing and dose criteria in 10 CFR 32.51. Thus, similar devices can be controlled under different regulatory schemes.

Reason for Choosing this Topic as a Case Study

The regulatory criteria for general versus specific license are not based on risk. The case study could illustrate how the application of risk information could improve a particular area of the regulatory process; also, this could be a test case for a safety goal on property damage.

Key Points

Effectiveness of Screening Criteria

- Provided a path to follow when attempting to make a decision about whether risk-informing the regulation of fixed gauges is feasible and/or desirable.

- Appeared to contain all the relevant considerations for making decisions as to whether to pursue risk-informing a proposed regulatory action. Application guidance will be an important tool for the staff to use when applying the screening criteria to future decisions.

Value of Using Risk Information; Process Improvements

- Case study demonstrated that using risk information can provide burden reduction and improve efficiency in decision making. It also pointed out that increased regulatory oversight may be warranted in some cases.

- Using risk information could benefit NRC, licensees, and the public by providing greater controls on devices which are more likely to cause harm. The approach would also allow resources to be focused in proportion to the risk a device presents. Staff would be given the tools needed to make a clear safety argument for their licensing and inspection decisions, and efficiency and effectiveness would be improved by reducing the review time necessary for special cases in licensing and device approvals.

Implicit/Explicit Safety Goals

- Safety goals for fixed gauges would be beneficial. They would enable the staff to make licensing and inspection decisions which are consistent and defensible. There appears to be no reason why safety goals could not be developed for occupational and accident risks.

- The manufacturer's design dose criteria found in 10 CFR 32.51 are elements of safety goals.

- Previous risk-informed staff decisions pertaining to approval of generally licensed devices, as well as staff decisions regarding clean up of sites contaminated by breaches of sealed sources, provide reference points for safety goals on accident risks.

Information, Tools, Methods, Guidance

- Several risk studies have been done for fixed gauges, and other similar devices, which use sealed sources of radioactivity. Compilation and comparison of these studies should result in a useable source of information to risk-inform the regulation of fixed gauges.

- Inferences may need to be made for the risk-informed regulation of fixed gauges from risk studies for other similar devices.

2.4 Case Study on Uranium Recovery

The uranium recovery process primarily consists of the milling and disposal aspects of uranium recovery after the uranium ore is removed from the ground. In a conventional mine, either deep mining or shallow open pit, the rock containing the uranium ore is removed and

processed at a uranium mill, where an extraction process concentrates the uranium into yellow cake. Uranium can also be leached out of the ground by pumping a water solution through wells to dissolve the uranium in the ore. The uranium is then pumped to the surface in a liquid solution, and then processed. Waste from milling operations are disposed of in a tailings pile. Mill tailings are fine-grained sand-like waste materials left over from uranium processing. Wastes from in-situ leach facilities may be disposed of in several ways, including release to surface water, evaporated from lined ponds, onsite applications (irrigation) or returned to the aquifers via deepwell injection.

The NRC does not regulate mining operations (deepwell or surface), and its regulations only apply to the ISL process and subsequent milling processes. NRC efforts for the uranium recovery program are governed by the Uranium Mill Tailings Radiation Control Act of 1978, as amended, and the applicable regulations of 10 CFR Part 40.

Reason for Choosing this Topic as a Case Study

Gaps in the regulations may be found; this may be helpful in testing the screening criteria. The case study could also illustrate how the application of risk information has improved or could improve the uranium recovery regulatory process.

Key Points

Effectiveness of Screening Criteria

- Revealed that chemical is the primary risk, and this risk is not presently regulated by NRC. These are only considered in terms of chemical accidents which may induce radiological events.

- Risk-Informing the regulatory process could be beneficial, but is not supported by industry due to depressed economic state of uranium recovery industry.

Value of Using Risk Information-Process Improvements

- Risk was used to evaluate various disposal options at a mill site.

- By identifying chemical as a potential risk, operators and regulators can focus resources on this area.

- ISL PRA showed importance of radiological and chemical safety and in maintaining integrity of aquifer against excursions from ore bed

Implicit/Explicit Safety Goals

- Prevent significant adverse impacts from radioactive waste to the current/future health of the environment. (GEIS, NUREG-0706)

- Maintain safety and protection of the environment. (GEIS, NUREG-0706)

- No significant adverse impact on occupational health from UR activities. (SECY 99-100)
- Maintain public confidence in Uranium recovery industry.(NRC Strategic Plan NUREG-1614)

Information, Tools, Methods, Guidance

- Site specific and generic EISs, ISAs and PRAs
- NMED Database
- Dose assessment models (RESRAD, MILDOS-AREA)
- ISL facilities have option for performance-based license approach

2.5 Case Study on Paducah Gaseous Diffusion Plant Seismic Upgrades

The Paducah Gaseous Diffusion Plant (GDP) is the only operating uranium enrichment plant in the United States. The facility is owned by the United Stated Enrichment Corporation (USEC), which was created by Congress in the 1992 Energy Policy Act. Under this Act, the oversight responsibility for the Paducah GDP is placed on the NRC. It is NRC's responsibility to establish safety, safeguards, and security regulations, and to certify the plant in accordance with 10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

Because of its close proximity to the New Madrid Seismic Zone, seismic safety became an important considerations in the certification of the Paducah GDP. The case study took a retrospective look at the activities undertaken by NRC and USEC to address the seismic issues associated with the plant. The case study examined how, and to what extent, risk information was used to resolve these seismic issues.

Reason for Choosing this Topic as a Case Study

Case study could provide insights on whether the use of risk information could improve the regulatory process for gaseous diffusion plants. This decision-making process will be a good test for the draft screening criteria and will help establish consistency in applying risk information across materials and waste programs. Also, chemical risks could be explored.

Key Points

Effectiveness of Screening Criteria

- Clearly showed that risk information was used and was applicable to decision making
- Helped to identify chemical risk as the important contributor
- Helped to identify implicit safety goals

Value of Using Risk Info; Process Improvements

- Established level of risk for particular facility
- Provided basis for Justification for Continuing Operation
- Identified and quantified seismic weak links

Implicit/Explicit safety Goals

- No significant impact on public health and safety
- No significant impact on worker health and safety
- No significant impact on the environment

Information, Tools, Methods, Guidance

- Several risk studies were performed for the certification process
- Extensions and adaptations of PRA methods
- 10 CFR 76 and applicable codes and standards

2.6 Case Study on Trojan Nuclear Plant Decommissioning

This case study focuses on the decommissioning of the Trojan Nuclear Power Plant and, more specifically, the License Termination Plan proposed by the licensee, Portland General Electric Company, the NRC License Termination Rule, and the review of the licensee's Plan by the NRC.

The Trojan Nuclear Power Plant operated from 1976 to 1992 and shutdown permanently in 1993. The licensee is now in the process of decommissioning the plant. Its objective is to obtain an unrestricted release of the site as per the requirements of 10 CFR 20, Subpart E, from its license. The LTP was prepared in accordance with 10 CFR 50.82 and the guidance provided in RG 1.179. The objective of the LTP is to demonstrate that the remainder of decommissioning activities will be performed in accordance with 10 CFR 50.82, and will not affect public health and safety and the quality of the environment.

Reason for Choosing this Topic as a Case Study

Trojan was the first decommissioning plant to submit an LTP under NRC's new License Termination Rule, which is considered to be risk informed.

Key Points

Effectiveness of Screening Criteria

- Risk Informed Approach of GEIS/LTR helpful in decision making for evaluating decommissioning options
- Trojan study showed that residual risk levels were extremely low
- Trojan decision to go for screening DCGLs reflected realistic appreciation of site risks

Value of Using Risk Information

- GEIS established value of risk approach to decommissioning
- LTR (Part 20 Subpart E) is risk informed
- Risk informed approach can help in analyzing options for restricted site release

Implicit/Explicit Safety Goals

- No significant additional impact on public/worker health from decommissioning
- No significant additional impact on environment
- Return site to pre-existing conditions
- Release site for unrestricted use
- Maximize number of sites for unrestricted release

Information, Tools, Methods, Guidance

- License Termination Rule (Part 20, Subpart E)
- NUREG-1727 Standard Review Plan
- DCGL Screening Values
- DandD, RESRAD codes for dose assessment to member of critical group
- MARSSIM, NUREG-1549 for compliance
- Performance Assessment in NRC paper

2.7 Case Study on the Transportation of the Trojan Reactor Vessel Package

This case study focuses on the shipment of an irradiated nuclear reactor vessel from the Trojan Nuclear Plant in Rainier, Oregon, to a low level waste disposal site in Richland, Washington. The shipment was one of the decommissioning activities for the Trojan Nuclear Plant, which permanently shutdown in 1993 after approximately seventeen years of operation.

Most of the shipment occurred by barge on the Columbia River; a small portion was by land transporter at the Hanford Reservation, where the disposal site was located.

The NRC approved the shipment based, in part, on probabilistic safety studies prepared by the licensee, Portland General Electric. The probabilistic safety studies provided the basis for the NRC granting an exemption to certain design requirements in 10 CFR Part 71, NRC's regulations for packaging and transporting radioactive materials. The exemption allowed the licensee to ship and dispose the Trojan reactor vessel as a whole with internals intact; thus, reducing radiation risk to workers and saving the licensee and area rate payers millions of dollars.

Reason for Choosing this Topic as a Case Study

Elements of existing, implicit safety goals may be found in Commission decisions; may also be a good case for examining public confidence and communication issues.

Key points

Effectiveness of Screening Criteria

- Appeared to contain all the relevant considerations for making decisions as to whether to pursue risk-informing a proposed regulatory action.
- Clarifying guidance is needed to make their use practical for the staff, and to make their intent clear to stakeholders.
- Would have identified this case as one which would benefit from risk information.

Value of Using Risk Information

- Case study showed the potential of risk information to provide for substantial burden reduction and improved staff efficiency in making decisions, at no increase in risk.
- As illustrated by this case, the alternative shipment method (intact by barge) that was justified by the risk analysis, was actually a substantial reduction in risk.
- 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, along with other benefits such as efficiency.

Implicit/Explicit Safety Goals

- Several risk metrics involved in the process of preparing, shipping, and disposing of the reactor vessel, including occupational exposure of workers and accident risks.
- The primary metric that was considered in the decision to permit the shipment was the 10-6 probability for the most likely accident. Thus, the staff decision that this was an

acceptable risk is a reference point for a safety goal on accidental risks with consequence levels similar to these.

- The licensee was able to calculate the 10-6 probability, but there was no guidance saying what would be acceptable. That is, safety goals are needed.

Information, Tools, Methods, Guidance

- Considerable resources available for estimating probabilities of transportation accidents. Statistical data exists from several sources, see the references.
- Calculating consequences of transport accidents might require quite sophisticated methods, depending on the type of transport package.

- Safety goals are needed; licensee uncertainty could be alleviated and staff decision making facilitated if a clear set of safety goals existed.

2.8 Case Study on Seismic Exemption for the DOE/INEEL TMI-2 ISFSI

In 1996, the Department of Energy (DOE) submitted to NRC an application for a license to build and operate an independent spent fuel storage installation (ISFSI) on its Idaho National Engineering and Environmental Laboratory (INEEL) site in Eastern Idaho. The ISFSI would be used to store the Three Mile Island Unit 2 (TMI-2) spent fuel debris which, at the time, was being stored in a spent fuel pool at INEEL. DOE's decision to transfer the TMI-2 fuel debris from wet storage to dry storage was motivated by concerns that, in the event of a leak, the spent fuel pool water could contaminate the nearby underground water sources.

As part of this application, DOE requested an exemption to the seismic design criteria specified in 10 CFR 72.102 (f)(1). This provision required that ISFSIs be designed to withstand an earthquake with peak ground acceleration (PGA) values evaluated by a deterministic method using Appendix A of 10 CFR Part 100, NRC's nuclear reactor site criteria. DOE proposed an alternative lower PGA value for its ISFSI and justified the lower value with results from deterministic and probabilistic seismic hazards analyses. NRC evaluated the results and concluded that the DOE's alternative PGA value provided adequate conservatism. Therefore, NRC granted a seismic exemption to DOE in 1998. The exemption allowed DOE to design the ISFSI based on a design earthquake with a PGA of 0.36g (instead 0.56, which was derived by a deterministic method). Cost savings for constructing a thinner concrete storage pad with fewer reinforcing bars were estimated to be several million dollars.

Prior to the TMI-2 ISFSI seismic exemption, NRC staff had proposed to revise 10 CFR Part 72 to incorporate the use of probabilistic seismic analysis in the earthquake PGA determination. The TMI-2 ISFSI seismic exemption emphasized the need for revising the 10 CFR Part 72 seismic design criteria for dry-cask ISFSIs. The staff has proposed to lower the design earthquake to a level that is commensurate with the lower risk associated with an ISFSI versus an operating nuclear power reactor.

Reason for Choosing this Topic as a Case Study

Implicit safety goals may be found in decisions and documents related to the probabilistic hazards analysis exemptions and proposed rulemaking. May also be a good case for examining public confidence issues and burden considerations.

Key points

Effectiveness of Screening Criteria

- This case study passed all the draft screening criteria. The draft screening criteria appeared to be effective in screening a potential application for risk-informing.

- To make better use of the screening criteria, it is suggested that the flow chart for criteria 5 and 6 be modified to read: "If the answer to criterion 5 (or 6) is yes, proceed to additional criteria; if not, the activity may be screened out pending the outcome of other criteria." Essentially, this modification allows the user to look at the screening criteria in their entirety and make a decision based on all the screening criteria.

Value of Using Risk Information; Process Improvements

- Risk information was used successfully by the Agency to support granting the licensee the seismic exemption in their TMI-2 independent spent fuel storage installation (ISFSI) application.

- This case study highlights the need to revise the 10 CFR Part 72 to accept the use of probabilistic seismic hazard analysis (PSHA) method so it will be consistent with 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

- The use of risk information in the seismic areas for future ISFSI applications is feasible. The use of risk information in the other areas of future ISFSI applications was not evaluated in this case study. It could probably be expanded into other areas.

Implicit/Explicit Safety Goals

- No explicit safety goals are found in the current regulations; however, the Part 72 Statements of Consideration recognized the risks of dry cask storage were lower than those at an operating nuclear power plant. Hence a different set of risk criteria for the ISFSI are reasonable.

- One possible safety goal could be that the human exposure to radionuclides should be lower for more frequently occurring events with smaller magnitudes (e.g., an earthquake with a 2,000-yr return period). Conversely, exposure to radionuclides should be higher for a less frequently occurring event (e.g., an earthquake with a 10,000-yr return period) with a larger magnitude. Regardless of the frequency of an event, all exposures should be less than the regulatory limits.

Information, Tools, Methods, Guidance

- Both deterministic and probabilistic seismic studies have been performed at various locations throughout the Idaho National Engineering and Environmental Laboratory site. The earlier studies (pre 1990) were of less quality because they were less location

3. INSIGHTS FROM CASE STUDIES

This section provides identifies insights that may be gleaned from comparing and contrasting the case studies. The NMSS staff will discuss these insights at the public workshop on October 25, 2001.

Effectiveness of Screening Criteria:

- Can be a useful decision-making tool, contained all relevant considerations
- Application can be subjective, guidance needed
- Should be Screening Considerations instead of Screening Criteria
- Can be finalized with few modifications and with guidance for its application

Value of Using Risk Information; Process Improvements:

- Helped staff to make decisions that were, in retrospect, consistent with the Agency's current strategic goals
- Can be useful in identifying shortcomings in our regulations or regulatory processes

Feasibility Safety Goals:

- Safety goals are feasible
- Decision-making can be facilitated if clear set of safety goals existed

Availability of Information, Tools, Methods, Guidance:

- Mixed; exist in some materials and waste areas, but may need to be developed in others