March 31, 1999 SECY-99-100

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: FRAMEWORK FOR RISK-INFORMED REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

PURPOSE:

To (1) address commitments made by the staff in SECY-98-138 and (2) request Commission approval of: (a) the staff's proposal to implement the framework for using risk assessment in regulating nuclear material uses and radioactive waste disposal; (b) the staff's proposed approach for addressing risk management issues in those areas and, in particular, its development of risk metrics and goals; and (c) the formation of a joint Advisory Committee on Reactor Safeguards (ACRS)/Advisory Committee on Nuclear Waste (ACNW) subcommittee to provide technical peer review of the staff's future efforts.

SUMMARY:

This paper addresses commitments made by the staff in SECY-98-138. It describes the results of an effort to scope the development of a framework for applying risk assessment methods to the regulation of nuclear material uses and waste disposal and makes recommendations to the Commission on how to proceed. It first discusses the risk assessment considerations that were

CONTACT: Seth M. Coplan, NMSS/DWM
(301) 415-5873

to comprise the scoping effort (i.e., an association of risk assessment methods with nuclear material uses and the regulatory use of such risk assessment methods). It next describes a proposed framework, steps for implementation of that framework, and reports the staff's conclusions about the value of current "Probabilistic Risk Assessment (PRA) Implementation Plan" activities in consideration of the proposed framework. The paper then discusses risk management issues related to nuclear material use and disposal, including the development and establishment of appropriate risk metrics and goals as part of implementing the framework. Finally, it discusses stakeholder involvement, technical support, and peer review. It recommends that the Commission approve (1) the staff's proposal to implement the framework and (2) formation of a joint ACRS/ACNW subcommittee to provide technical peer review of the staff's future efforts.

BACKGROUND:

In SECY-95-280, the staff informed the Commission of its framework for applying PRA in reactor regulation. This framework provides a general structure to ensure consistent and appropriate application of PRA methods in regulating nuclear reactors. Since the reactor framework was transmitted in November 1995, the offices of Nuclear Reactor Regulation (NRR) and Nuclear Regulatory Research (RES) have made substantial progress toward completing the six-step process that was envisioned to implement it.

In its staff requirements memorandum (SRM) of April 15, 1997, about risk-informed (RI) and performance-based (PB) regulation, the Commission included direction to the staff to: (1) review its RI and PB approaches with regard to high-level radioactive waste (HLW) issues and nuclear material uses to assure that the needs of those licensees and areas receive adequate consideration; (2) review the bases for nuclear materials regulation to identify areas that can be made amenable to RI or PB regulation with minimal additional resources; and (3) develop a framework for applying PRA to nuclear material uses similar to the reactor framework. SECY-98-138 provided a preliminary response to the SRM. The staff concluded that the first two of these requests could not be addressed fully until a framework had been at least partially developed. The staff further concluded that: (1) the reactor framework was not directly applicable because of differences among the activities regulated by the Office of Nuclear Material Safety and Safeguards (NMSS) and collectively between those activities and reactors; and (2) development of an appropriate framework could be a substantial effort that would need to involve the Agreement States (AS') and other stakeholders. The staff informed the Commission that, given U.S. Nuclear Regulatory Commission's (NRC's) available resources, it would first use a task group (TG) to scope the development of a framework, estimate the requisite resources, and make a recommendation to the Commission on how to proceed. For the scoping effort, the staff proposed to: (1) make a preliminary association of risk assessment methods with regulated uses of nuclear material; and (2) as appropriate for each regulated use and in coordination with the AS', make a preliminary identification of how the associated risk assessment method could be used in a risk-informed regulatory framework for nuclear materials regulation.

Part of the staff's response to the April 15, 1997 SRM was the establishment of a NRC/AS' Working Group, the Nuclear Byproduct Material Risk Review (NBMRR) Group, to identify and document a technical basis for a risk-informed approach to regulation of certain material and to develop plans for a graded approach to regulation of that material using risk information. A

companion paper, SECY-99-062, "Nuclear Byproduct Material Risk Review," describes, in greater detail, one of the risk assessment methodologies that is discussed in this paper. Earlier papers provided detailed descriptions of other risk assessment methodologies that are discussed in this paper and apply principally to applications of nuclear materials. More specifically, SECY-94-228 described performance assessment (PA) and SECY-98-185 described integrated safety analysis (ISA).

DISCUSSION:

The staff has completed the proposed scoping effort using a TG drawn from each of the divisions of NMSS and from the offices of NRR and RES[1] (the TG members and their organizational affiliations are listed in Attachment 1). This paper discusses the results of the scoping effort and makes recommendations to the Commission on a framework for the use of risk assessment in nuclear materials regulation. These recommendations address issues related both to risk assessment [i.e., the variety of assessment methods that are now in use or could be used (and how these are or might be used) in RI regulation] and risk management (i.e., the establishment of metrics and goals for risk to appropriate individuals or groups). The framework proposed is consistent with the Commission's "PRA Policy Statement" and, at a high level, parallels the framework adopted for reactor regulation. The objectives of the materials framework are the same as for the reactor framework: (1) enhance safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety; (2) provide a framework for using risk information in all regulatory matters; and (3) allow use of risk information to provide flexibility in licensing and operational areas. Although risk management issues were not identified as part of the scoping effort in SECY-98-138, they are discussed in this paper because the staff found that uses of risk assessment to meet these three objectives in regulating nuclear materials could be limited by an important policy gap relative to the reactor situation. Specifically, the Commission's "Safety Goals for the Operations of Nuclear Power Plants Policy Statement" established important risk metrics and goals for the reactor program and in that way provided a risk management foundation for subsequent use of PRA. No similar policy statement exists for material uses and disposal and, in consequence, the need to consider development of an analogous foundation is discussed in this paper.

Association of Risk Assessment Methods with Nuclear Material Uses

Broadly, the activities regulated by NMSS can be categorized in four groups: (1) activities that involve long-term commitment of a site or facility to the presence of nuclear material at a planned, acceptable level (e.g., HLW disposal); (2) activities that involve use of engineered casks to isolate nuclear material under a variety of normal and off-normal conditions (e.g., transportation and storage); (3) activities that involve physical and chemical processing and possession of nuclear material at a large-scale facility (e.g., fuel fabrication); and (4) activities that involve the use of either sealed or unsealed byproduct material in a wide variety of industrial and medical applications. Not surprisingly, these groups correspond closely to the organization of NMSS. Their differences from one another include: the facilities, systems, or devices employed; potential exposure pathways; potential accident initiators and frequencies; potential consequences; and populations at risk. Systematic analysis of these specific features

[1]The AS' were asked to participate in the TG effort; however, they decided that their direct participation in the closely related NBMRR along with being kept informed of TG progress would meet their needs adequately.

is the crux of any risk assessment that might be applied to an NMSS-regulated activity. Therefore, different risk assessment methods are more efficient and effective for the activities of each group. Such methods have been developed or adapted from methods used for other similar technologies as the need has arisen. Accordingly, the degree of development of and experience in using these methods differs.

Geologic disposal of radioactive wastes, site cleanup, and mill tailings reclamation constitute group 1. Starting in the mid-1970s, the staff has been a developer of PA methodology for the assessment of risk associated with deep geologic disposal of HLW, land disposal of low-level radioactive wastes (LLW), and residual site contamination after decommissioning. From the beginning of the HLW and LLW programs, it was recognized that risk insights that can be derived using PA are particularly well-suited to address issues that arise from the long-term nature of HLW and LLW disposal. Thus, NRC's existing regulations for deep geologic disposal of HLW (10 CFR Part 60) and land disposal of LLW (10 CFR Part 61) both anticipate the use of PA methodology to show compliance with long-term performance objectives for those facilities. A similar reliance on PA is an essential feature of site-specific regulations that are now being developed for HLW disposal at Yucca Mountain (10 CFR Part 63). More recently, NRC amended 10 CFR Part 20 to establish criteria for residual contamination at decommissioned sites. The staff is currently developing risk-informed guidance to implement these criteria.

Transportation and storage, particularly of spent fuel, comprise group 2. The staff made early efforts to apply risk assessment methodology for the analysis of transportation risk--most notably, the "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170), and "Shipping Container Response to Severe Highway and Railway Accident Conditions" (NUREG/CR-4829, also known as the "Modal Study"). More recently, the staff has applied PRA methodology in deciding to approve the one-time shipment of the Trojan reactor pressure vessel, with internals, for disposal at the U.S. Ecology site in the State of Washington. Also, the staff has nearly completed its re-validation of NUREG-0170 in light of proposed shipments to a repository (vs. reprocessing). The re-validation effort should be completed by the last quarter of fiscal year (FY) 1999 and includes a computer evaluation of cask response to severe accidents and probabilities, the use of current health effects models, and studies of population distributions about likely shipment routes. The staff intends to use the results of the NUREG-0170 re-validation in its efforts to update the Modal Study for the new generation of dual-purpose cask designs. The Modal Study update will focus on confirming severe accident probabilities and effects and will likely include partial or full-scale package tests. Moreover, the staff intends to encourage more RI decision-making with the U.S. Department of Transportation and the International Atomic Energy Agency (IAEA). The staff believes that ISA and PRA are both appropriate risk assessment methodologies for transportation.

Dry cask storage is the other major group 2 activity. The staff thinks that ISA or PRA can be an appropriate risk assessment tool for this activity as well. At one point, the staff wanted to apply PRA to dry cask storage systems with staff and contractor resources, but suspended the project when the resources were needed for high-priority licensing and certification efforts. In lieu of this broad project, an initial ISA was developed by the staff for one particular dry cask storage system which, in essence, was a general scoping risk assessment of the vulnerabilities of this cask system. The report is currently under peer review and will be issued later this year.

Although this appears to be an effective early risk assessment, further development of an ISA or PRA will be constrained, based on available staff resources.

Fuel fabrication, uranium enrichment, and mining and milling of source material exemplify group 3. There are several ongoing efforts to develop appropriate risk assessment methods for the processes included in this group. First, the staff and the major fuel cycle licensees have adapted risk assessment technology that was developed for the chemical process industry after the Bhopal accident. This adaptation, ISA, has proven to be an integrated hazard identification and assessment methodology for major fuel cycle facility operations. The staff and these licensees have been working to develop a regulatory approach using ISAs, and substantial progress has been made in that regard. In June 1999, the staff expects to transmit proposed revisions to 10 CFR Part 70 incorporating this approach for Commission approval. These proposed revisions will be the result of extensive staff and industry consideration of how the ISA concept should be applied to fuel cycle facilities, and the staff expects that it will be generally supported by the industry. Second, the staff and the U.S. Department of Energy (DOE) plan to use ISA technology to support design and operation of the pre-closure facilities related to a geologic repository for HLW. Such use is incorporated in the proposed Part 63. The staff is sponsoring a project at the Center for Nuclear Waste Regulatory Analyses (CNWRA) to develop guidance for the review of the pre-closure safety analysis for the repository, based on the ISA methodology. Finally, the CNWRA is starting a project to assess the risks associated with in situ leach extraction of Uranium. Risk insights gained from this project will be used to support risk-informed rulemaking for such facilities.

Industrial radiography, nuclear medicine, and well-logging exemplify group 4. With respect to risk assessment, the situation regarding the wide variety of activities in this group is complex. In the early 1990s, the staff tested the use of PRA methodology to study the risk associated with a new medical procedure (gamma stereotactic surgery). The results were positive, but the approach was expensive and had some significant limitations. Although the PRA correctly predicted human error to be the principal accident initiator, the fault tree/event tree methodology was an inadequate tool for analyzing such accidents. Recently, the staff started the NBMRR in partial response to the SRM of April 15, 1997. The principal objective of the NBMRR was to develop the basis for a risk-graded approach to regulating the activities in group 4. This involved the development of appropriate risk assessment methods to address these activities. The staff believes that the project has resulted in significant progress in that regard and has provided the Commission with a more detailed description in SECY-99-062, “Nuclear Byproduct Material Risk Review,” dated March 1, 1999.

Definitions of these risk assessment methods and a table that displays their specific association with the activities comprising these four groups are provided as Attachment 2 to this paper.

Use of Risk Assessment Methods in a Risk-Informed Regulatory Framework

The “PRA Policy Statement” provides general guidance on what regulatory use should be made of risk assessment. Implementation of this general guidance can be accomplished by a variety of approaches involving staff and licensee use of risk insights and risk assessment in regulatory decision-making. In each case, there are two principal considerations: (1) What specific use is the staff expected to make of risk insights and risk assessment in development of regulations and guidance, licensing, inspection, assessment, and enforcement? and (2) What specific use

is the licensee expected to make of risk insights and risk assessment in planning and conducting its operations? A number of factors are important to these two considerations. They relate primarily to what can be gained in terms of safety and reduction of regulatory burden, on the one hand, versus the cost of transition and ultimate implementation, on the other. These factors were discussed in SECY-98-138 and include: hazard and complexity of the activity, degree of human involvement in the activity, technical sophistication of the licensee community, NRC staffing and training issues, AS issues, and others. Consideration of these factors in the context of the full variety of NMSS-regulated activities must involve stakeholders and can be expected to result in a number of specific approaches, each of which would be appropriate for the specific activity. Some of these approaches make or will make qualitative use of risk assessment to supplement traditional approaches (e.g., approach for regulating low-activity, sealed sources); others make or will make quantitative and more sophisticated use of such methods (e.g., the HLW approach). A tabulation of current staff thinking regarding such approaches is provided in Attachment 3. This tabulation was developed only as part of the scoping effort. It is preliminary and is likely to change substantially as the framework proposed below is implemented.

A Proposed Framework

During its deliberations about the appropriate scope of a nuclear materials framework, the TG developed a framework that is applicable to the materials area. This framework, described in Attachment 4, is similar to the reactor framework, but adopts a lower level of specificity. Like the reactor framework, It is a high-level structure that leaves the particulars of establishing and implementing specific risk-informed approaches to a series of implementation steps. These steps are also described in Attachment 4. Progress toward completing them would be reported and tracked in the ”PRA Implementation Plan.” With Commission approval, the staff will begin implementation of the framework described in Attachment 4.

Current PRA Implementation Plan Activities in Consideration of the Framework

The SRM of April 15, 1997, requested that the staff re-examine its RI/PB approaches with regard to nuclear material licensees and to HLW issues, to ensure that the needs of those licensees and those areas receive adequate consideration. In Attachment B to Attachment 1 of SECY-98-138, the staff provided its preliminary response by re-examining the approaches that are supported by Tasks 4 and 5 of the “PRA Implementation Plan.” The staff considered this response to be preliminary because it believed that some conclusions and priorities could have changed as work on a framework progressed. The staff now has re-examined these same approaches, given its proposed framework, and sees no reason to change its preliminary analysis and conclusions. Moreover, as is discussed above, the staff now expects to add activities to the “PRA Implementation Plan” if the Commission approves its framework.

Risk Management

Risk management for NMSS must achieve the overall regulatory goal--safety in the use and disposal of radioactive material. A fundamental element of risk management is to determine which risks to estimate [what are the risk metrics (i.e. what activity produces the risk, what individual, group, or property receives the risk, what conditions produce the risk)] and to determine what limits are acceptable (i.e., risk goals) for these various risks. In addition risk

management would involve using risk insights to evaluate and manage aspects of the regulatory program in various programmatic areas, such as licensing, inspection, and rule changes.

Risk Management Metrics and Goals for Nuclear Material Uses and Disposal

In developing risk metrics a fundamental aspect is whether the risk arises from normal operations with the attendant low-level exposure of workers and the public or whether the risk arises from upset or accident conditions [this is designated normal exposure and potential exposure by the International Commission on Radiation Protection (ICRP)]. For both power reactor operation and material uses, the risk metrics and goals have been established for normal operations by international and national standards-setting organizations (such as ICRP and the National Committee on Radiation Protection and Measurements (NCRP)) and further incorporated into law and regulation. For upset and accident conditions at power reactors, the Commission's "Safety Goals for the Operations of Nuclear Power Plants Policy Statement" establishes two qualitative safety goals that are supported by two quantitative health objectives (QHOs). The QHOs are supported, in turn, by two subsidiary risk goals for core damage frequency and large early release frequency. Although it is attractive to consider the QHOs and analogues of the subsidiary risk goals for material risk management, this is not feasible, because of differences in the population at risk, the number of uses regulated, the nature and behavior of the systems regulated, and hazards posed by reactors versus material uses. Therefore, the materials program must develop its own set of safety goals. Furthermore, because of the substantial differences among the various material uses, separate safety goals for each activity regulated under each program area must be contemplated. It should be noted that this approach could result in different risk goals (or levels of protection) being applied to different regulated activities; however, any such goals would provide reasonable assurance of adequate public protection.

At a minimum, the risk metrics and goals must address the safety of workers and the general public for normal operations. It should be noted that, in the materials area, the risk associated with normal operation (especially for workers) tends to be large compared with the risk from accidents (e.g. see Table S-4, 10 CFR 51.52). Metrics and goals for normal operations have been established in terms of radiation dose. They apply for all activities and sources and include:

Population at Risk	**Risk Metric**	**Risk Limit**	**Regulation**
Workers	Annual dose	0.05 Sv (5 rem) and ALARA[2]	Part 20
Public	Annual dose	1 mSv (0.1 rem) and ALARA	Part 20

Under the overarching public risk limit, more restrictive limits have been established or are being considered for specific activities or sources. For example, a 0.25 mSv/year (25 mrem/yr)

[2]ALARA is the acronym for "as low as is reasonably achievable."

and ALARA limit has been established in Part 20 for public doses from residual radioactivity at formerly licensed sites and a 0.25 mSv/year (25 mrem/year) and ALARA limit has been established in Part 61 for public doses resulting from land disposal of LLW. Similarly, 0.01 mSv/year (1 mrem/yr) is being considered as a limit for public doses as a result of recycling of previously contaminated material.

The challenging part of establishing risk goals for materials uses, as for reactors, will be the upset or accident goals. In developing the reactor safety goals, NRC considered such factors as the population at risk surrounding each reactor, the number of reactors, and probability of severe accidents at those reactors. These same factors are important for establishing materials safety goals. For materials, the population at risk depends on the specific use, is quite variable, and can be quite large. For example, a large portion of the entire U.S. population is at risk from transportation accidents; a smaller, but still large population group is at risk from medical procedures (primarily from diagnostic procedures). In contrast, the population at risk from the proposed repository at Yucca Mountain is comparatively small. The number of material licensees (~20,000) and number of sources for potential accidents are large compared with the number of power reactors (~75). Because there are so many more regulated sources, even if the accident rates were comparable to reactor accident rates, the numbers of incidents would be much larger. Since some of these accidents could be, and indeed have been, fatal, the safety goals for material uses must consider the large numbers involved and the likely adverse public reaction that a number of radiation-induced fatalities would engender, even if the risk were low. On the other hand, few material uses involve as much radioactivity as a power reactor and none has the high temperature and pressure that contribute to the greater hazard of the reactor source term. In sum, the risk associated with power reactors derives primarily from low-probability, high-consequence, events, whereas the risk from material uses and disposal derives primarily from higher probability, low-consequence, events. Because of these differences in the nature of the risks, it is appropriate to use different safety goals and different risk management strategies in the two arenas. Some risk metrics that might be useful for materials uses include: (1) overall risk of individual fatality from a particular material use for the appropriate population at risk (both workers[3] and members of the public); (2) frequency of large exposures [e.g., exposures in excess of the dose limit for Abnormal Occurrence reporting–0.25 Sv/yr (25 rem/year)] for a particular material use; (3) the maximum dose possible from a particular material use given reasonably conservative assumptions (i.e., a dose cap); and (4) the probability of a criticality event at a facility using fissile material. It is premature to suggest risk goals to correspond to these metrics.

In addition to these substantial technical issues, a number of other factors must be considered in developing specific risk management strategies and the risk-informed regulatory approaches that would incorporate such strategies for materials regulation. First, developing, setting, and implementing radiation protection standards is shared by NRC with other stakeholders, including: (1) the U.S. Environmental Protection Agency (EPA) and other Federal agencies; (2) State governments (which, in some specific cases, have statutory authority to set and implement more restrictive standards than those established by EPA); and (3) independent

[3]It should be noted that the safety goals for reactors do not address worker safety. For many, if not most, material uses, the risk to workers is the principal aspect of the risk and, therefore, much of NMSS' regulatory effort is directed toward worker protection from both accidents and normal exposure. Accordingly, risk metrics and goals for nuclear material uses would address worker protection from accidents.

standards-setting entities such as ICRP, NCRP, and IAEA. Therefore, NRC must accommodate these shared functions in developing a risk management approach and assure an appropriate level of communication with, and acceptance by, these stakeholders. Second, material licensees have a quite variable level of capability in risk assessment, different levels of resources available for all regulatory matters, and different levels of interest in pursuing a risk-informed approach. Except for a few such licensees (e.g., the DOE Yucca Mountain Project), material licensees do not have a significant capability in probabilisitic safety assessment methods and do not have the attendant sunk costs for their development; this is different from the situation for power reactors. These variations in capabilities, resources, and interest must be factored into any RI regulatory approach selected for a particular area of material use. Thus, as part of the evaluation of alternative RI regulatory approaches, careful consideration must be given to: (1) the costs, both to the staff and licensees, of implementing a new approach; and (2) the benefits, in terms of risk reduction and/or elimination of unnecessary regulatory burdens. Consistent with these technical and programmatic considerations, the series of implementation steps that are described in Attachment 4 for the proposed nuclear materials framework include consideration of risk management issues.

The variability in target populations, standard-setting authorities, and existing dose limits (and thus in implied risk metrics and goals) is illustrated by the table in attachment 5.

Stakeholder Involvement, Technical Support, and Peer Review

Implementation of the proposed framework and risk management approach will affect the public, other government agencies (at all levels), and licensees. Accordingly, the staff considers that a broad range of input will be needed to effectively expand the use of RI regulatory approaches in the materials area. To assure appropriate consistency across NRC, important aspects of implementation will be coordinated with the PRA Steering Committee. When changes to an existing regulatory approach are contemplated, the staff plans to minimize the impact on NRC and stakeholder resources by: (1) seeking stakeholder involvement through public workshops, Internet postings, and pilot projects; (2) using technical consultants to supplement its own expertise; and (3) establishing a mechanism for technical peer review. For peer review, the staff believes that a joint ACRS/ACNW subcommittee (with appropriate input from the Advisory Committee on the Medical Use of Isotopes) could best integrate a knowledge of RI approaches in the reactor area and an understanding of materials issues into its reviews. The staff has discussed this matter with the Executive Director of the ACRS and the ACNW. He agrees with the staff's recommended approach and with Commission approval would form such a subcommittee.

RESOURCES:

To fully implement the approach described above, the staff in each NMSS program area would conduct most of the resource-intensive activities. These would include: evaluating the risk aspects of a programmatic area; interacting with stakeholders; making the appropriate changes to the regulations, staff review plans, and Regulatory Guides; training; and developing or adapting needed tools. This would entail an effort of 5 full-time equivalents (FTEs) per year for 5 years starting in FY 2000. In addition, a small cadre of material risk experts would be needed to facilitate the activities in various areas and assure an appropriate degree of consistency across NMSS and within NRC. This would require an additional 3 FTEs per year starting in FY

2000. In FY 2000, although no FTEs have been budgeted, $400,000 has been budgeted for contractor technical assistance which would provide approximately 2 FTEs of contractor support for the effort. If the Commission approves the staff's recommendations, the remaining unbudgeted 6 FTE would be reprogrammed from other, as yet, unidentified NMSS efforts in FY 2000.

Some support would also be needed from OGC and ACRS/ACNW. Estimated resources for these offices are 0.2 FTE and 0.5 FTE per year, respectively. Although the OGC and ACRS/ACNW budgets for FY 2000 did not include resources for this effort, these offices will reprogram resources from within their currently available budgets if the Commission approves the staff's recommendations. Resources to fully implement this effort in FY 2001 and beyond will be addressed during the FY 2001 budget formulation process.

RECOMMENDATION:

That the Commission approve: (1) the staff's proposal to implement the framework set forth in Attachment 4 for using risk assessment in regulating nuclear material uses and disposal; (2) the staff's proposed approach for addressing risk management issues in those areas and, in particular, its development of risk metrics and goals; and (3) formation of a joint ACRS/ACNW subcommittee to provide technical peer review of the staff's future efforts.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The interoffice senior level PRA Steering Committee was briefed on this paper and its comments have been appropriately incorporated.

William D. Travers
Executive Director
for Operations

Attachments:
1. Task Group Members
2. Definition of Terms
3. Potential Regulatory Use of Risk Assessment Methods
4. A Framework for Applying Risk Assessment to Regulating Nuclear Material Uses and Disposal
5. Summary of Dose Limits and Target Populations

the staff's recommendations. Resources to fully implement this effort in FY 2001 and beyond will be addressed during the FY 2001 budget formulation process.

RECOMMENDATION:

That the Commission approve: (1) the staff's proposal to implement the framework set forth in Attachment 4 for using risk assessment in regulating nuclear material uses and disposal; (2) the staff's proposed approach for addressing risk management issues in those areas and, in particular, its development of risk metrics and goals; and (3) formation of a joint ACRS/ACNW subcommittee to provide technical peer review of the staff's future efforts.

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NAME	FMiraglia		WTravers		JLarkins/email					
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ATTACHMENT 1

TASK GROUP MEMBERS

Office of Nuclear Material Safety and Safeguards:

Stephen Koenick, Division of Fuel Cycle Safety and Safeguards
Dennis Serig/John Telford, Division of Industrial and Medical Nuclear Safety
Norman Eisenberg, Division of Waste Management
Lawrence Kokajko, Spent Fuel Project Office
Seth Coplan (Chair), Division of Waste Management

Office of Nuclear Regulatory Research:

Nathan Siu, Division of Systems Technology

Office of Nuclear Reactor Regulation:

Gareth Parry, Division of Systems Safety and Analysis

ATTACHMENT 2

DEFINITION OF TERMS

Virtually all the safety assessment and compliance analysis tools used in the Office of Nuclear Material Safety and Safeguards (NMSS) are a variety of systematic safety assessment methods. A subset of these systematic safety assessment methods are Probabilistic Safety Assessment (PSA) methods. Because the terminology is not standardized and because each group of users of such methods tends to use terms to stress a particular aspect of the methodology or its application, a variety of terms have been developed and employed in various applications. The following definitions are provided for clarification:

System Analysis - System analysis is a directed process for the orderly and timely acquisition and investigation of specific system information pertinent to a given decision. (Fault Tree Handbook, 1981)

Probabilistic Safety Assessment (PSA) - A wide class of probabilistic methods used to assess safety; this includes probabilistic risk assessment (PRA), risk assessment, failure mode and effects analysis, and performance assessment (PA).

Risk - The risk triplet is the set, $<s_i, f_i, x_i>$, in which s_i represents the ith scenario (sequence or progression); f_i is the associated frequency; and x_i is the resulting consequence. (S. Kaplan and B. J. Garrick, "On the Quantitative Definition of Risk")

Risk Assessment (RA) - "Risk Assessment refers to the technical assessment of the nature and magnitude of risk." (from: “Risk Analysis: A guide to principles and methods for analyzing health and environmental risks.” J.J. Cohrssen and V.T. Covello, CEQ, 1989)

Probabilistic Risk Assessment - "Probabilistic Risk Assessment is an analytical technique for integrating diverse aspects of design and operation in order to assess the risk of a particular nuclear power plant [facility] and to develop an information base for analyzing plant-specific [facility-specific] and generic issues. In achieving these objectives, probabilistic risk assessments serve many purposes." (from PRA Procedures Guide, 1982.) Note, this is a definition of PRA focused on U.S. Nuclear Regulatory Commission (NRC) reactor activities and is used as a term of art, within NRC, to denote analyses of reactor safety, usually with considerable detail regarding the component and system failures that lead to an accident. In some cases the plant systems analysis (Level I PRA) is expanded to include an analysis of accident progression and source term (Level II PRA) and further expanded to include consequence analysis and risk integration (Level III PRA) A broader community uses PRA to mean a broader variety of analyses devoted to other systems and with a wider range of complexity and detail.

Performance Assessment (PA) - PA, a type of systematic safety analysis, is a method: (1) to estimate the potential health, safety, and environmental effects of creating and using a nuclear waste facility; (2) to characterize these effects in terms of their magnitude and likelihood; (3) to compare the characterization of these effects with acceptability standards; and (4) to present the results of these analyses in a format useful to regulators, scientists, and the public. (Adapted from N. A. Eisenberg, et al., “A proposed validation strategy for the U.S. DOE Office of Civilian Radioactive Waste Management geologic repository program,” GEOVAL 1987) PA, as used programmatically in NMSS, includes any quantitative assessment or modeling

performed to evaluate a waste facility or part thereof, regardless of the degree to which the analysis is probabilistic.

Total System Performance Assessment (TSPA) -"Performance assessment is a method of forecasting how a system or parts of a system designed to contain radioactive waste will behave over time. Its goal is to aid in determining whether the system can meet established performance requirements. A TSPA is the subset of performance assessment analyses in which all of the components of a system are linked into a single analysis." (U.S. Department of Energy (DOE), "Viability Assessment of a Repository at Yucca Mountain, Total System Performance Assessment." 1998) This is clearly a term of art used by DOE to emphasize the complete nature of the analysis. It should be noted that although a TSPA must calculate some measure of total system performance, it may also calculate (most analyses do calculate) the performance of subsystems or provide intermediate results.

Integrated Safety Analysis (ISA) - An ISA is a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences; the potential accident sequences and their likelihood and consequences; and the items (i.e., site, structures, systems, equipment, components, and activities of personnel) that are relied on for safety. This methodology, adapted from the chemical process industry, provides for flexibility in the scope and detail of the analysis, depending on the magnitude of the hazards and the nature of the system. This method has been used in NMSS to address the safety in fuel fabrication facilities and in spent fuel storage facilities.

ASSOCIATION OF RISK ASSESSMENT METHODS WITH REGULATED USES OF NUCLEAR MATERIALS

Group	Description	Regulated Activities	Risk Assessment Method
1	Activities that involve long-term commitment of a site or facility to the presence of nuclear material at a planned, acceptable level	-High level waste (HLW) disposal -Low level waste (LLW) disposal -Decommissioning (residual contamination) -Mill tailings reclamation	Performance Assessment
2	Activities that involve the use of engineered casks to isolate nuclear material under various normal and off-normal conditions	-Transportation -Dry cask storage	Probabilistic Risk Assessment or Integrated Safety Analysis (ISA)
3	Activities that involve chemical and physical processing of nuclear material at a large-scale facility	-Mining and milling of source material -Uranium hexaflouride conversion -Enrichment -Fuel fabrication -Pre-closure activities related to HLW and LLW disposal -Waste treatment facility (vitrification)	ISA
4	Activities that involve the use of either sealed or unsealed byproduct material in industrial and medical applications	-Irradiators -Radiography -Medical Uses -Well Logging -Laboratory Use -Manufacturing and Distribution -Gauges -measuring Systems -Waste Disposal (incineration, packaging processing)	Hazard/Barrier Analysis (Nuclear Byproduct Material Risk Review assessment methodology)

ATTACHMENT 3

POTENTIAL REGULATORY USE OF RISK ASSESSMENT METHODS

Group	Activity	Regulatory Manifestation of Risk Insights	Licensee Use of Risk Assessment	Staff Use of Risk Assessment
1	High-level waste (HLW) disposal	Probabilistic dose standard codified by rule	Performance assessment (PA) to show compliance with standard	PA to develop risk insights in support of rulemaking and development of guidance. PA to support independent review of licensee's analysis
1	Low-level waste (LLW) disposal	Dose standard, for reasonable scenarios, codified by rule	PA to show compliance with standard	PA to develop risk insights in support of development of guidance. PA to support independent review of licensee's analysis
1	Decommissioning (residual contamination)	Dose standard, for reasonable scenarios, codified by rule	PA to show compliance with standard. Guidance will permit simplified analysis in most cases.	PA to develop risk insights in support of development of guidance. PA to support independent review of licensee's analysis
1	Mill tailings reclamation	Uranium Mill Tailings Radiation Control Act and associated Environmental Protection Agency standards establish an immutable basis	None	None
2	Transportation	Performance-based criteria and guidance and risk-informed regulatory decisions (e.g., Trojan vessel) derived from risk insights	Applicant/licensee may perform risk assessment to support regulatory actions (e.g., Trojan reactor vessel).	Probabilistic risk assessment (PRA) or Integrated Safety Analysis (ISA) to develop risk insights that underpin regulations and guidance
2	Dry cask storage	Performance-based criteria and guidance and risk-informed regulatory decisions derived from risk insights	Applicant/licensee may perform risk assessment to support regulatory actions.	PRA or ISA to develop risk insights that underpin regulations and guidance
3	Mining of source material	Prescriptive criteria and guidance derived from risk insights	None	ISA to develop risk insights that underpin regulations and guidance
3	Milling of source material	Prescriptive criteria and guidance derived from risk insights	None	ISA to develop risk insights that underpin regulations and guidance
3	UF-6 conversion	Performance requirements comprised of radiological consequences, given the likelihood of occurrence	ISA summary to demonstrate compliance with performance requirements	ISA summary forms the basis for regulatory activities.
3	Enrichment	Performance requirements comprised of radiological consequences, given the likelihood of occurrence	ISA summary to demonstrate compliance with performance requirements	ISA summary forms the basis for regulatory activities.
3	Fuel fabrication	Performance requirements comprised of radiological consequences given the likelihood of occurrence.	ISA summary to demonstrate compliance with performance requirements.	ISA summary forms the basis for regulatory activities.
3	Pre-closure activities for HLW disposal	Dose standard for normal operations and a spectrum of likely scenarios	ISA to show compliance with dose standards	ISA to support independent review of any licensee analyses that may bear significantly on post-closure repository performance
3	Pre-closure activity for LLW disposal	Dose standard for normal operation and prescriptive requirements for off-normal conditions	None	None

3	Waste treatment facility (vitrification)	Performance requirements comprised of radiological consequences, given the likelihood of occurrence.	ISA summary to demonstrate compliance with performance requirements	ISA summary forms the basis for regulatory activities.
4	Sealed Sources	Regulatory requirements ranging from exemption to specific licensing criteria	None	Ongoing refinement to develop risk insights that underpin regulations, licensing and inspection practices, and guidance
4	Unsealed Byproduct Material	Regulatory requirements ranging from exemption to specific licensing criteria	None	Ongoing refinement to develop risk insights that underpin regulations, licensing and inspection practices, and guidance

ATTACHMENT 4

A FRAMEWORK FOR APPLYING RISK ASSESSMENT TO REGULATING NUCLEAR MATERIAL USES AND DISPOSAL

1. THE REACTOR FRAMEWORK OF SECY-95-280

As described in SECY-95-280, the reactor framework is a general structure to ensure consistent and appropriate application of probabilistic risk assessment (PRA) methods. It has four parts. The first defines regulatory application areas (e.g., graded quality assurance) in which PRA can play a role in the U.S. Nuclear Regulatory Commission's (NRC's) decision-making process. The areas are grouped by the expected sophistication of the PRA required (ranging from PRAs based on generic data to state-of-the-art PRAs using plant-specific data). The second part entails an evaluation of the deterministic engineering considerations underlying the application area to ensure that the existing deterministic engineering approach is altered only after careful consideration. Factors to be considered include: defense-in-depth, the single-failure criterion, and appropriate codes and standards. The third part of the framework is an evaluation of risk issues in support of the proposed regulatory action. Elements of this evaluation include: scope and level of detail of the PRA, human and equipment reliability, sensitivity and uncertainty analyses, and assurance of technical quality. The final part integrates the deterministic and risk considerations to ensure a consistent and scrutable decision-making process and to ensure that the underlying bases for rules, regulations, regulatory guides, and staff review guidance are maintained or modified to the extent supported by the risk and engineering conclusions of parts two and three.

This framework is implemented through a six-step process. The first step is to identify the specific regulatory applications that are amenable to expanded use of PRA information and to identify responsible staff organizations and pilot plants. The second is to conduct pilot programs for selected regulatory application areas. These projects provide insight into the treatment of issues, the selection of risk metrics, and the development of standards and guidance. The third step of the implementation process is to develop and document the acceptance process and criteria. The fourth step is to make near-term regulatory decisions in response to industry requests and initiatives. The fifth is to develop formal PRA standards, working with appropriate professional societies and industry groups. Finally, the sixth step is to make long-term modifications to the regulations, if necessary.

2. RISK ASSESSMENT IN MATERIALS REGULATION--COMPARISON WITH REACTORS

SECY-98-138 discussed the following differences between the nuclear materials and reactor programs in terms of developing a framework for using risk-assessment in nuclear materials regulation:

1. PRA may be applicable only for a few nuclear material uses; other risk assessment methods may be needed for most such uses;

2. Integrating probabilistic and deterministic considerations is not as important in regulating nuclear material uses as it is in reactor regulation;

3. Relating analytical methods to specific applications is much more important for materials applications;

4. A broad range of licensee and regulator circumstances will need to be considered.

3. A FRAMEWORK FOR NUCLEAR MATERIAL USES AND DISPOSAL

These differences are addressed by a framework that is quite similar to the reactor framework of SECY-95-280. It too has four parts. Like the reactor framework, the first part defines regulatory application areas in which risk assessment methods can play a role in NRC's decision-making process. The areas are grouped by regulated use (e.g., fuel fabrication) and within each use by regulatory application (e.g., graded quality assurance). The second part entails an evaluation of the current considerations underlying the application area to ensure that the existing approach is altered only after careful consideration. Factors to be considered include: deterministic considerations [hazard, relative importance of human vs. equipment error, defense-in-depth (where applicable), codes and standards];, current risk considerations (e.g., use of performance assessment in geologic repository licensing); and institutional considerations (existing statutory requirements, Agreement State issues, and licensee circumstances). The third part of the framework is an evaluation of new risk considerations in support of the proposed regulatory action. Elements of this evaluation include: scope and level of detail of the risk assessment, sensitivity and uncertainty analyses, and assurance of technical quality. The final part integrates the current considerations and new risk considerations to ensure a consistent and scrutable decision-making process and to ensure that the underlying bases for rules, regulations, regulatory guides, and staff review guidance are maintained or modified to the extent supported by the conclusions of parts two and three.

This framework will be implemented through a five-step process. The first step is to identify the specific regulatory applications that are amenable to expanded use of risk assessment information and to identify responsible staff organizations. This step would be accomplished by identifying a full set of regulatory application areas as defined above and then screening them to establish a set of applications that would be amenable to risk-informed (RI) regulatory approaches. The staff would intend to systematically evaluate all of its regulatory applications in this manner, but external considerations would be used to prioritize which would be treated first. For example, the staff is currently working with an RI approach for total system performance of a geologic repository for high-level radioactive waste (HLW) because of external considerations regarding the national HLW program. Because of limited resources, the staff is proposing this step-by-step approach, rather than a comprehensive reevaluation in all areas simultaneously. On this prioritized basis, the technical and programmatic factors affecting the choice of risk metrics and goals in each regulatory application area would be systematically evaluated. Consideration would be given to: (1) the costs, both to the staff and licensees, of implementing a new approach; and (2) the benefits, in terms of risk reduction and/or elimination of unnecessary regulatory burdens. This evaluation would use predictive or actuarial risk studies, as appropriate. Given these considerations, the staff would decide whether it seems appropriate to change the existing regulatory framework and, if so, propose risk metrics and goals as a basis for interaction with stakeholders. Such interaction would include stakeholder workshops, Internet postings, and possibly pilot projects.

The second step is to decide how to modify the current approach of the regulatory application areas that are determined to be amenable to RI approaches. Stakeholder workshops, Internet postings, and pilot projects will be used as an important source of information to address the following considerations: (1) what specific use is the staff expected to make of risk insights and risk assessment in development of regulations and guidance, licensing, inspection, assessment, and enforcement? and (2) what specific use is the licensee expected to make of risk insights and risk assessment in planning and conducting its operations? The third step is to make the appropriate changes to the rules and regulations, staff review plans, and Regulatory Guides. Where feasible, the staff would encourage industry development of voluntary standards. The fourth step is staff training to assure consistent and knowledgeable implementation of the new RI approaches, and the fifth step is to develop or adapt needed tools (e.g., risk assessment methods or computer codes). This five-step implementation process is shown in Figure 1.

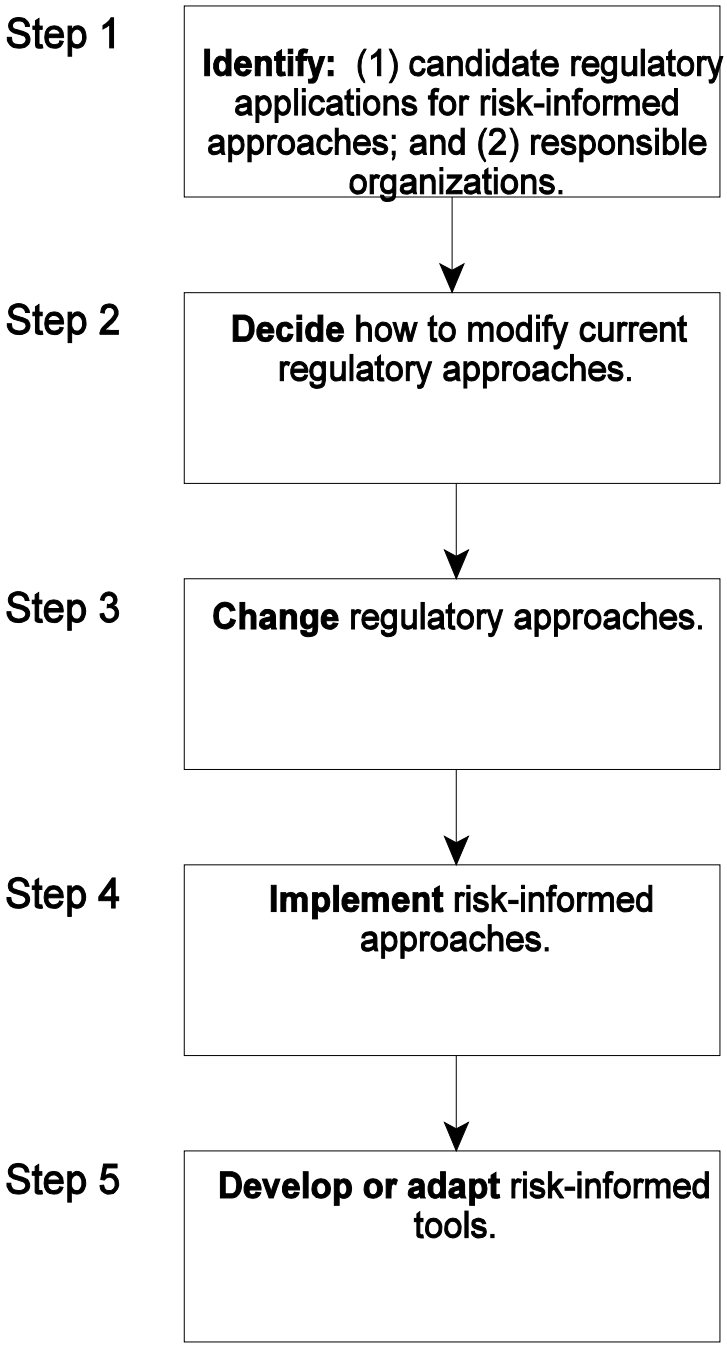

Figure 1. Five-step implementation process.

ATTACHMENT 5

Summary of dose limits & target populations

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
500 rem	ICRP & NCRP recommendation	Max equivalent dose to the skin of an occupational workers for emergency life-saving efforts	NCRP #116 (p. 44)
400 rem	NCRP Recommendation	Career Male astronaut whole body dose equivalent limit[1]	NCRP #98 (p. 7)
300 rem	NCRP Recommendation	Career Female astronaut whole body dose equivalent limit[1]	NCRP #98 (p. 7)
300 rem	10 CFR 100	Max total radiation dose for a 2 hour period to the thyroid from a postulated fission product release if an individual were present at any point of a nuclear reactor's exclusion area boundary	10 CFR 100.11(a)(1)
250 rem	NCRP Recommendation	Theoretical occupational Lifetime dose	NCRP #98 (p. 7)
100 rem	NCRP Recommendation	Whole body dose for life-saving actions (valid until 1986)	NCRP #39[2] (p. 100)
50 rem	ICRP & NCRP Recommendation	Max effective dose to an occupational worker for emergency life-saving efforts	NCRP #116 ICRP 60
50 rem	10 CFR 20	Annual organ or tissue dose other than lens of the eye; Shallow dose equivalent to the skin or any extremity	10 CFR 20.1201
>25 rem	EPA Protective Action Guides	Voluntary Whole body dose for life-saving actions & protection of large populations	EPA-400-R-92-001 (May 1992)
25 rem	10 CFR 100	Max total radiation dose for a 2 hour period to the whole body from a postulated fission product release if an individual were present at any point of a nuclear reactor's exclusion area boundary	10 CFR 100.11(a)(1)
25 rem	EPA Protective Action Guides & USNRC RG 8.29	Whole body dose for life-saving actions & protection of large populations	EPA-400-R-92-001 (May 1992); RG 8.29 (p.13)
25 rem	10 CFR 20 & 10 CFR 835	Lifetime dose limit for individuals participating in planned special exposures	10 CFR 20.1206(e)(2) & 10 CFR 835.204

[1] Career whole body dose equivalent limit at age 55 based on a lifetime excess risk of cancer mortality of 3×10^{-4} per rad.

[2] NCRP Report No. 39 (1971) has been superseded by NCRP report No. 116 (1993)

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
18.75 rem	29 CFR 1910	Max quarterly dose for hands and forearms; feet and ankles (osha-regulated activities)[3]	29 CFR 1910.96 (b)
15 rem	10 CFR 20	Annual eye dose equivalent (lens of the eye)	10 CFR 20.1201
10 rem	USNRC RG 8.29	Acute emergency exposure for protecting valuable property	RG 8.29 (1996) (p. 8.29-13)
10 rem	NCRP Recommendation	Acute emergency exposure for life-saving actions	NRCP # 91 (p. 36)
7.5 rem	29 CFR 1910	Max quarterly dose to skin of whole body of occupational workers (osha-regulated activities)	29 CFR 1910.96 (b)
5 rem	10 CFR 20 & 10 CFR 835	Annual Exposure Limit for Occupational Workers (NRC, DOE & States)	10 CFR 20.1201 & 10 CFR 835.202
5 rem	10 CFR 72	Max whole body dose to any individual located on or beyond the nearest boundary of the controlled area of an ISFSI or MRS[4]	10 CFR 72.106
5 rem	10 CFR 35	Notification limits for medical misadministrations involving members of the public	60 FR 48623 (Oct 1995)
3 rem	29 CFR 1910	Max quarterly dose to the whole body (OSHA-regulated activities)	29 CFR 1910.96
2 rem	EPA	Remedial annual action level for naturally occurring radiation (radon) for members of the public (corresponds to 2 WLM[5])	NCRP #116 (p. 49)
1.875 rem	OSHA	Max quarterly hand or forearm dose to a minor (under age 18)	29 CFR 1910.96(b)(3)
1.5 rem	IAEA Recommendation	Threshold for conducting environmental monitoring and assessments of radiation exposure levels in work areas due to the transport of radioactive material	IAEA Safety Series #6 (1985)

[3] OSHA-Regulated activities include occupational exposure from facilities other than those regulated by nrc or an agreement state. These may include radiation exposures from x-rays or linear accelerators operated by non-agreement states.

[4] ISFSI = Independent Spent Fuel Storage Installation; MRS = Monitored retrievable storage installation

[5] One working level month (WLM) is approximately equal to an annual exposure to an average of 4 pCi per liter of radon if the radon products are in 50% equilibrium with the radon. One WLM exposure would result from being exposed to 1 working level (WL) for a period of 1 working month (i.e. 170 hrs)

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
1.25 rem	49 CFR 172	Max quarterly EDE for occupational radiation exposure resulting from transportation activities	49 CFR 172.803 (b)(1)
1 rem	---	Avg astronaut Exposure per Flight Mission	NCRP #94
1 rem	EPA	EPA public protection action guide limit for evacuation & shelter	EPA 400-R-92-001 (pp. 2-6)
750 mrem	OSHA	Max quarterly skin of whole body dose to a minor (under age 18)	29 CFR 1910.96(b)(3)
650 mrem	---	Avg ede[6] per diagnostic Nuclear brain scan	NCRP #93 (p 46)
540 mrem	10 CFR 20[7]	Avg annual measurable dose per radiographer (1993)[8]	NUREG-0713 Vol 15 (p. 4-6)
500 mrem	10 CFR 35	Proposed patient release criteria	SECY-96-100 & NUREG-1492
500 mrem	10 CFR 20, 10 CFR 835 & 49 CFR 172	Max dose equivalent limit to the embryo/fetus (entire gestation period)	10 CFR 20.1208, 10 CFR 835.206 & 49 CFR 172.803 (b)(3)
500 mrem	ANSI, Non-agreement State regs	Design criteria for shielding for radiation-producing machines (i.e., teletherapy, x-ray machines, irradiators)	ANSI N433.1 & NCRP #49
500 mrem	NCRP Recommendation	Max annual effective dose limit for infrequent annual exposures to members of the public	NCRP #116 (p. 46)
500 mrem	NCRP Recommendation	remedial annual action limit recommended for continuous exposures from natural sources (excluding radon)	NCRP #116 (p. 50)
500 mrem	49 CFR 172 & EPA FRC Guidance[9]	Max annual radiation exposure to members of the general public from transporting radioactive material	49 CFR 172.803 (b)(2) IAEA Safety Series #6
360 mrem	---	Annual TEDE for public (including annual medical exposure)	NCRP #101 (p. 73)

[6] EDE = Effective dose equivalent

[7] Resultant Average dose from the application of regulatory requirements in 10 CFR Part 20 (i.e., ALARA)

[8] Number of radiographers monitored for radiation exposure in 1993 was 4720.

[9] EPA's Federal Radiation Council (FRC) guidance was issued in 1960. EPA is currently developing guidance for regulatory agencies for limiting radiation exposures to members of the general public, and the anticipated annual limit is expected to be 100 mrem/yr. however, as of 1996, this new EPA guidance document has not been issued.

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
300 mrem	---	Annual TEDE for public (Excluding annual medical exposure)	NCRP #94
270 mrem	10 CFR 20[10]	Avg annual measurable occupational dose per worker at LWRs (1993)[11]	10 CFR 20.1201
200 mrem	---	Avg annual dose to members of the public from radon	NCRP #93, #116 (p. 59; 45)
160 mrem	OSHA	Avg annual dose equivalent to Airplane Crew Members	NCRP #94 (p. 22)
125 mrem	OSHA	Max quarterly whole body dose to a minor (under age 18)	29 CFR 1910.96(b)(3)
100 mrem	10 CFR 20 & 10 CFR 835	Max annual Dose limits for members of the public	10 CFR 20.1301 & 10 CFR 835.208
100 mrem	IAEA B.S.S.[12]	Max annual dose equivalent for non-radiation workers (& shielding design specifications)	IAEA Safety Series 115-I
100 mR/wk	49 CFR 172	Max weekly radiation exposure to members of the public from transportation of radioactive material	49 CFR 172.803 (b)(2)
85 mrem	Proposed 40 CFR 196	Max dose "cap" to an individual for restricted use (EPA's proposed decommissioning std)	SECY-96-082 & Proposed 40 CFR 196.11 (d)(2)
75 mrem	10 CFR 72	Max annual dose equivalent to the thyroid of any real individual located beyond the controlled area resulting from radioactive materials in effluents and direct radiation from an ISFSI or MRS	10 CFR 72.104
50 mrem	10 CFR 20 App B, Tbl 2	Annual TEDE to members of the public resulting from the inhalation or ingestion of radionuclides continuously for a year	Part 20
50 mrem	29 CFR 1910	Max TEDE from inhalation or ingestion to a minor (under age 18) (Refs to 10 CFR 20)	29 CFR 1910.96(c)(2)
25 mrem	10 CFR 20	Licensees (i.e., fuel cycle facilities) subject to EPA's generally-applicable environmental radiation standards in 40 CFR 190	10 CFR 20.1301(d) & 40 CFR 190.10

[10] Resultant average dose in 1993 from the application of regulatory requirements in 10 CFR Part 20 (i.e., ALARA)

[11] Total number of commercial LWR workers monitored for radiation exposure in 1993 was 169,862. NUREG-0713, Vol 15, p.4-6.

[12] IAEA B.S.S.= International Basic safety standards for protection against ionizing radiation and for the safety of radiation sources, Safety Series No. 115-I (1994).

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
25 mrem	10 CFR 40, App A	Max annual public dose equivalent cannot exceed 25 mrem whole body, 75 mrem thyroid, and 25 mrem to any other organ as a result of exposure to planned discharges of radioactive materials, Rn-220 and its daughters excepted to environment.	10 CFR Part 40, Criterion 8
25 mrem	10 CFR 61	Max offsite releases to any member of the public for both operations and post-closure are limited to 25 mrem whole body, 75 mrem thyroid, & 25 mrem other organ	10 CFR 61.41
25 mrem	10 CFR 72	Max annual dose equivalent to the whole body or other organ of any real individual located beyond the controlled area resulting from radioactive materials in effluents and direct radiation from an ISFSI or MRS	10 CFR 72.104
25 mrem	40 CFR 190	Annual dose equivalent shall not exceed 25 mrem whole body, 75 mrem thyroid, & 25 mrem other organ as the result of planned discharges from uranium fuel cycle operations to the environment.	40 CFR 190.10
25 mrem	NCRP Recommendation	Max annual exposure to members of the public from a single source or set of sources under one control	NCRP #116 (p. 47)
20 mrem	---	Max individual public exposure due to transportation of radioactive material	NCRP #92 (p. 165)
20 mrad	10 CFR Part 50 Appendix I	Max annual beta air dose from gaseous effluents at any location near ground level from each LWR for any individual occupying an unrestricted area	10 CFR 50, App I Section II (B.1.)
15 mrem	Proposed 40 CFR 196	Annual EDE from all exposure pathways from a decommissioning site	40 CFR 196.11
15 mrem	10 CFR Part 50 Appendix I	Max annual organ dose or dose commitment from radioactive iodine or RAM in particulate form from effluents release from each LWR for any individual occupying an unrestricted area	10 CFR 50, App I, Section II (C.)
10 mrem	---	Avg annual effective dose equivalent to individuals in the U.S. from consumer products	NCRP #93 (p. 59)
10 mrad	10 CFR Part 50 Appendix I	Max annual gamma air dose from gaseous effluents at any location near ground level from each LWR for any individual occupying an unrestricted area	10 CFR 50, App I Section II (A)
10 mrem	EPA's clean air act	Max dose limit to members of the public from radioactive air effluents resulting from facilities regulated under this subpart	40 CFR Part 61, Subpart I
10 mrem	10 CFR Part 50 Appendix I	Max annual organ dose or dose commitment from liquid effluents from each LWR for any individual in an unrestricted area	10 CFR 50, App I Section II (A)

Dose or Dose Limit	Regulatory Basis	Target Population	Reference
4 mrem	Proposed 40 CFR 196	Max annual dose to any internal organ or the total body[13] corresponding to individual MCLs specified in 10 CFR 141 for protection of groundwater at a remediated site	40 CFR 196.23 (1) (See also 40 CFR 141.16)
3 mrem	10 CFR Part 50 Appendix I	Max annual total body dose or dose commitment from liquid effluents from each LWR for any individual in an unrestricted area	10 CFR 50, App I Section II (A)
2 mrem in any one hr	10 CFR 20	Max Dose Limit to members of the public in an unrestricted area from external sources[14]	10 CFR 20.1301 (a)(2)
2 mR/hr	10 CFR 71	Max external radiation level for packages in any normally occupied space (i.e., location of driver transporting radioactive material)	10 CFR 71.47 (b)(4)
2 mR/hr	49 CFR 172	Max radiation exposure to members of the general public from transportation of radioactive material	49 CFR 172.803 (b)(2)
1 mrem	IAEA Safety Series	Max annual individual dose equivalent per source or practice within the range of risks to be considered "Trivial." Also called "negligible individual dose (NID)"	IAEA Safety Series 89; IAEA-TECDOC-855 & NCRP #116 (p. 5)

[13] The 4 mrem/yr groundwater standard is derived from the average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water which would produce an annual dose equivalent of 4 mrem to the total body or any internal organ (see 40 CFR 141.16). NBS Handbook 69 (Aug 1963) is used as the basis for deriving these quantities, and each vary from the 4 mrem standard (For example., the MCL for Sr-90 = 0.07 mrem/yr; the MCL for uranium = 0.7 mrem/yr).

[14] In the statements of consideration for the revised 10 CFR Part 20 (see 56 FR 23374), the reason stated for the inclusion of the dose rate limit of 2 mrem in any one hour was that the limit "provides a more readily measurable quantity than the 100 mrem/yr value and can be more easily verified by short-term measurements."

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10 CFR Part 20 (NRC regulations)
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10 CFR Part 50 (NRC Regulations)
10 CFR Part 835 (DOE Regulations)
29 CFR Part 1910 (OSHA Regulations)
40 CFR Part 61 (EPA Regulations)
40 CFR Part 190 (epa Regulations)
40 CFR Part 196 (EPA Regulations)
49 CFR Part 172 (DOT Regulations)