

February 24, 2000

SECY-00-0048

FOR: The Commissioners

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

SUBJECT: NUCLEAR BYPRODUCT MATERIAL RISK REVIEW

PURPOSE:

To provide the Commission with a response to Staff Requirements Memoranda (SRM) dated April 13, 1998, and December 21, 1998 (Attachment 1) and to provide the staff's approach for use of the technical document NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (Attachment 2). This approach incorporates the insights and information from the risk assessment into Nuclear Material Safety and Safeguards (NMSS) wide risk efforts, which are discussed in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards."

SUMMARY:

This paper provides the Commission with the completed risk analysis for nuclear byproduct material uses and discusses the staff's plans for use of the risk analysis. Additionally, the paper discusses specific issues involving general licenses that have been addressed in two SRMs.

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BACKGROUND:

As a result of its Strategic Assessment efforts, the Commission determined that the U.S. Nuclear Regulatory Commission (NRC) needs to focus its activities in a more risk-informed, performance-based manner. The Commission issued several SRMs providing such direction to the staff (Attachment 1).

In 1997, the staff initiated a process for the development and implementation of a risk analysis methodology appropriate to the systems regulated under 10 CFR Parts 30-36 and 39. The Nuclear Byproduct Material Risk Assessment Review Group (hereafter, referred to as the Risk Review Group or the Group) was established to begin this process. The Group last reported to the Commission on March 1, 1999, in SECY-99-062, "Nuclear Byproduct Material Risk Review" (Attachment 3). As discussed in that paper, the scope of the Risk Review Group's activities encompassed byproduct materials as defined in Section 11.e(1) of the Atomic Energy Act of 1954 and regulated under 10 CFR Parts 30-36 and 39. The Risk Review Group focused the risk assessment on nuclear byproduct material systems. The systems categorized similar uses, types, forms, and quantities of materials together, regardless of the current regulatory basis. Working with a contractor, a risk assessment methodology was developed, implemented, and used to develop options for regulating materials activities. The staff informed the Commission that the Nuclear Byproduct Material Risk Study was one piece of the overall approach to making the regulation of nuclear byproduct material risk-informed. The overall approach was provided to the Commission in a separate Commission paper, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards" (SECY-99-100, dated March 31, 1999, Attachment 4).

A survey was performed of NRC and Agreement State personnel who perform inspection and licensing of byproduct materials activities, as described in SECY-99-062. The results of this survey are reported in NUREG-1712, "Nuclear Byproduct Material Risk Review, Results of Survey of NRC and Agreement State Materials Licensing and Inspection Personnel" (Attachment 5). The staff compared the aforementioned results with the results of the risk study in the Risk Review Group Report, which is discussed below (Attachment 6). As indicated in SECY-99-062, the staff published the results of the survey for public comment at the same time as NUREG/CR-6642.

DISCUSSION:

As requested in the SRM dated April 13, 1998, the staff is providing a copy of NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (Attachment 2). This is the technical-basis document for the risk assessment of activities authorized by 10 CFR Parts 30-36 and 39. A hazard-barrier-target analysis was selected for the quantitative assessment of radiological risk. The underlying concept involves hazards (radionuclides); barriers (defined in this study to include both engineered and administrative barriers or controls); and targets (workers and members of the public). The risk assessment methodology is specifically discussed in Chapter 2, along with Appendix A, in the NUREG/CR. Chapter 3 of the NUREG/CR contains a summary of risk results by system, for each of the 40 systems. Each system is divided into the following five subsections: (1) overview; (2) hazards; (3) tasks, barriers and receptors; (4) risk analysis; and (5) regulatory options.

Radiological risks of various activities were assessed using a single method so that the resulting risk values could be compared. In this study, dose and risk values are both expressed in terms of millirem/rem, but the risk values are NOT synonymous with dose because the risk value includes probability, a unitless number, as a factor. This study presents risk values for comparison only, and does not represent a judgement as to what risk values are acceptable at this time. Although ranking the various activities in order of risk allows easy identification of activities having higher risk, such a ranking provides insufficient information to identify where changes in regulation would be most effective. The risk values alone do not provide a sufficient basis for changing regulation of activities, because they do not consider radiological consequences that may be too high to tolerate at even low to moderate probabilities. If radiological risk values are to be used in developing changes to the regulations, acceptable levels of risk will need to be defined. This is part of the larger project within the scope of SECY-99-100. The Commission, in the SRM on SECY-99-100, directed the development of a safety goal for materials use; a necessary step in this process.

It is important to note that the risk values resulting from this study have uncertainties of one or more orders of magnitude. This is due to factors such as the lack of information about activities, uncertainties in available information, human factors and performance, and uncertainties in the models used. The uncertainties are discussed in more detail in Attachment 6, the Nuclear Byproduct Materials Risk Review Group Report.

The results of the radiological risk assessments for individuals under normal conditions were compared with the current dose limits, and with the current assignment of inspection priority for each system. This study did not identify any radiological consequences that were previously unknown. The study concluded that risk values under normal conditions are several orders of magnitude greater than the risk values under off-normal conditions. The study also concluded that, under normal conditions, the risk values to individual workers are 10 to 100 times greater than the risk values to members of the public. The risk values for activities performed under normal conditions are typically less than one-tenth of the 10 CFR 20 dose limits of 5,000 millirem per year to workers and 100 millirem per year to members of the public.

The report from the Risk Review Group on the risk assessment project is provided in Attachment 6. The report discusses, in detail, the: (1) scope of the risk assessment and the development of the systems; (2) uncertainties in dose and risk calculations; (3) method of risk assessment; (4) survey of materials licensing and inspection personnel; and (5) results of the risk assessment. The Risk Review Group report also discusses the strengths and weaknesses of the NUREG/CR.

Staff Plans for Use of NUREG/CR-6642

The NUREG/CR is: 1) being reviewed for safety issues needing prompt action; 2) being used as part of the Planning, Budgeting, Program Management (PBPM) process; and 3) going to be used in ongoing activities for using risk assessment in regulating nuclear material uses; one of which is the revision of licensing guidance as part of the NUREG-1556 Guidance Consolidation Project.

The staff performed a review of NUREG/CR-6642 to identify any safety issues, not currently addressed by regulation or policy, that require prompt action. The staff did not identify any

areas of regulation, policy, or programs (e.g. licensing/inspection) in need of immediate revision to address a safety issue in any of the systems.

The risk assessment NUREG/CR will be used to support the NRC in accordance with the Nuclear Materials Safety chapter of the strategic plan. As part of this PBPM process, the staff identified four performance goals: maintain safety, protection of the environment and the common defense and security; increase public confidence; make NRC activities and decisions more effective, efficient and realistic; and reduce unnecessary regulatory burden on stakeholders. For each of these four performance goals, the staff identified strategies for achieving the goals and for assessing success. Several of the strategies are directed toward making the NMSS activities more risk-informed and performance-based. Work currently being performed in the Nuclear Materials Safety area will be evaluated to determine which goal it supports and whether it is necessary and sufficient to accomplish the goal(s). The nuclear byproduct risk review will contribute to this process in a number of ways. For example, the insights from the report will be used to prioritize existing work, eliminate work that does not contribute to the goals, and identify new work necessary to achieve the goals.

The technical basis of the risk assessment will be incorporated into the staff's ongoing activities of the Risk Assessment and Management Section addressing SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999 (Attachment 4). The staff plans to use the information and insights from the nuclear byproduct risk review to evaluate work activities and make recommendations regarding restructuring the current materials licensing and inspection program. Additionally, the NUREG/CR will be used to identify and prioritize those areas, in the nuclear byproduct materials program, where decreased oversight of low-risk activities is warranted, as well as a continued emphasis on high-risk activities. As a result of the staff's use of the NUREG/CR, changes to the regulations may be indicated to improve the nuclear byproduct materials program. NRC will continue to involve the Agreement States in any program changes that might impact the States.

One ongoing work activity is the update of the "NUREG-1556 series Guidance Consolidation" project, which provides licensing and inspection guidance to specific licensees. The staff plans to incorporate the findings of NUREG/CR-6642 into the next revision of the guidance consolidation documents, which will occur over the next 3-4 years, beginning in 2000. This will include a review of relevant regulations to determine where changes in regulation are required, as well as in licensing and inspection guidance.

Issues Involving General Licenses

In an SRM dated April 13, 1998, the Commission directed the staff to: 1) consider the findings of the materials risk assessment to determine whether additional generally licensed devices should be subject to registration and follow-up; and 2) review the basis of the general licenses for adequacy with respect to consideration of the consequences of off-site accidents, such as loss of shielding or melting in metal-making furnaces. The SRM dated December 21, 1998, SECY-98-232, "Seaman Nuclear's Application for a License to Distribute Portable Moisture Density Gauges to General Licensees," directed the staff to evaluate 10 CFR 32.51(a)(2)(iii), as part of the Materials Risk Study, regarding consequences of losses and subsequent accidents of such devices, and whether an amendment to this regulation was needed. It also directed the staff to consider the results of the Materials Risk Study and what effect the staff's recommendations from the Risk Study have on the proposed license for Seaman Nuclear.

As to whether additional generally licensed devices should be subject to registration and follow-up, the staff conducted a review of the risk study and did not find any additional generally licensed devices that triggered a need for registration on the basis of safety. The staff is currently working on the final rule for requiring general licensees to provide requested information about their sources/devices. The staff is developing a registration process for generally licensed devices. At this time, the NRC plans to register only those general licensees with devices that present a higher risk in accordance with criteria established by an NRC/Agreement State working group and reported in October 1996, "Final Report of the NRC-Agreement State Working Group to Evaluate Control and Accountability of Licensed Devices." Additionally, a database is being developed for all generally licensed devices. The staff will be reporting the status of this project to the Commission in mid-2000.

The staff reviewed the basis of the general licenses for adequacy with respect to consideration of the consequences of off-site accidents, such as loss of shielding or melting in metal-making furnaces. The staff also evaluated 10 CFR 32.51(a)(2)(iii) regarding consequences of losses and subsequent accidents of such devices, and whether an amendment to this regulation was needed. Although the risk study identified a need for assurance that shielding and confinement of all sealed sources be maintained, and a need for assurance that sources are not lost, the staff does not see an immediate need to change the regulations. For both situations, the level of assurance needed increases with the radiological consequence. In general, the risk study found that there is little radiological consequence to the public from contamination resulting from airborne releases or radioactivity due to smelting or crushing of sources. However, there may be significant radiological consequence to individuals of the public in close proximity from a large gamma source that is unidentified in the public domain, whether or not the source is intact. Large alpha- or beta-emitting sources have some potential for radiological consequence to individuals of the public if the source containment is breached. Therefore, there may be a need to include consideration of lost sources in 10 CFR 32.51(a)(2)(iii), but this needs to be reviewed in context with the implementation of the new registration program and the results it achieves.

The SRM dated December 21, 1998, requested the staff to consider the results of the Materials Risk Study and what effect the staff's recommendations from the risk study have on Seaman Nuclear's license application for a general license. The staff is currently working on this issue, and will be submitting a paper to the Commission in June 2000.

RESOURCES:

Resources to conduct the risk review activities discussed in this paper are included in the budgets for fiscal year (FY) 2000 and FY 2001. Resources for FY 2002 and beyond will be addressed as part of the FY 2002 budget formulation process.

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 Office of the Chief Information Officer has reviewed this paper for information technology and information management implications and has no objections. The

staff has provided a copy of this paper as well as NUREG/CR-6642 to the Joint Advisory Committee on Reactor Safeguards/Advisory Committee on Nuclear Waste Subcommittee for their comments and recommendations on the risk study and the staff's planned approach for using the results. The staff will continue to coordinate risk activities with this Subcommittee as necessary.

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Attachments:

1. Summary of SRMs with copies of SRMs
2. NUREG/CR-6642
3. SECY-99-062, dtd 3/1/99
4. SECY-99-100, dtd 3/31/99
5. NUREG 1712
6. Report from Nuclear Materials Risk Assessment Review Group
7. Matrix summary of risks

ADAMS # ML003678058 **(This is package containing all attachments)**

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OFC	RGB	C	RGB	C	IMNS	TechEd	NMSS	DEDMRS	EDO
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SUMMARY OF SRMS

SRM dated March 20, 1997, “COMSECY-96-057, Materials/Medical Oversight” (DSI 7)

Issued in response to Direction Setting Issue 7 (DSI 7), “Materials/Medical Oversight”

Stated that the NRC supports continuation of the existing medical oversight program (with improvements) and for decreased oversight of low-risk activities with a continued emphasis in high-risk activities. It stated, in part, that “NRC would utilize the risk-informed performance-based approach, as discussed in DSI 12, to determine which activities in the materials area, and specifically in the medical area, are low-risk activities.”

SRM dated April 15, 1997, COMSECY-96-061, “Risk-Informed, Performance-Based Regulation” (DSI 12)

Issued in response to Direction Setting Issue 12 (DSI-12), “Risk-Informed “Risk-Informed, Performance-Based Regulation”

The Commission indicated that, in the future, the regulatory focus should be on those licensee activities that pose the greatest risk to the public. It further indicated that accomplishment of that focus would depend on increased use of probabilistic risk assessment concepts or other approaches that would allow a graded approach for determining high- and low-risk activities. The staff was directed to identify and prioritize areas of nuclear material regulation that were, or could be made amenable to, risk-informed, performance-based, or risk-informed, less-prescriptive, approaches, with minimal additional staff effort/resources.

SRM dated April 13, 1998, SECY-97-273, SECY-96-221, “Improving NRC’s Control Over, and Licensees’ Accountability for, Generally and Specifically Licensed Devices”

Related to “Improving NRC’s Control Over, and Licensees’ Accountability for, Generally and Specifically Licensed Devices”

Item 4 of this SRM states, in part, that the staff should “Use the results of the materials risk assessment study to restructure the current licensing and materials program. Consider the findings when determining whether additional sources/devices should be subject to registration and follow-up, and for performing the risk ranking necessary if a phase-in approach is used...Review the basis of the general licenses for adequacy with respect to consideration of the consequences of off-site accidents...provide the technical basis document for the risk assessment together with recommendations on how to proceed.”

SRM dated December 21, 1998, SECY-98-232, “Seaman Nuclear’s Application for a License to Distribute Portable Moisture Density Gauges to General Licensees”

Related to SECY-98-232, “Seaman Nuclear’s Application for a License to Distribute Portable Moisture Density Gauges to General Licensees”

The Commission directed the staff to consider the results of the Materials risk Study and what effect the staff’s recommendations from the Risk Study have on the proposed license for Seaman Nuclear. Additionally, as part of the Materials Risk Study, the staff was directed to review 10 CFR 32.51(a)(2)(iii) and consequences of losses and subsequent accidents of such devices, and provide the Commission with its review along with recommendations as to whether this section of the regulations should be amended.