January 17, 1997

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FROM: John H. Austin, Chief
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SUBJECT: POSITION PAPER ON RISK-ASSESSMENT IN NMSS

By memorandum dated October 23, 1996, Dr. Paperiello requested the Division of Waste Management to prepare a position paper on the use of risk-assessment in NMSS, based on inputs from the other Divisions and the Spent Fuel Project Office. Attached is a draft of the paper. An actual position will be considered after Dr. Paperiello reviews the paper. I would appreciate any comments you have on the draft by January 31,1997, particularly any additional examples of risk-informed, performance-based regulation that is underway.

Attachment: As stated

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RISK-ASSESSMENT IN NMSS

PURPOSE

By memorandum dated October 23, 1996, the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) asked the Division of Waste Management (DWM) to prepare a position paper on the use of risk-assessment in NMSS, based on inputs from the other Divisions and the Spent Fuel Project Office (SFPO). The genesis of the request is the desire of the Commission to increase the use of probabilistic risk assessment (PRA) methods in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data, and in a manner that complements NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy (60 FR 42622).

BACKGROUND

In the Commission's Strategic Assessment and Rebaselining initiative, one of the Direction Setting Issues is Risk-Informed, Performance-Based Regulation (DSI 12). In that issue paper, the Commission expressed its preliminary view which states in part:

> The staff should also perform a thorough review of the basis for nuclear materials regulations and process, and should identify and prioritize those areas that are either now, or can be made with minimal additional effort/resources, amenable to a risk-informed, performance-based approach. This assessment should eventually lead to the development of a framework for applying PRA to nuclear material uses, similar to the one developed for reactor regulation (SECY-95-280), where appropriate.

The referenced framework (SECY-95-280) for expanded use of PRA in reactor

regulation has four parts. The first part defines regulatory application areas in which PRA can play a role in the agency's decision-making process, with the areas grouped by the expected sophistication of the PRA required (ranging from PRA's based on generic data to state-of-the-art PRA's based on plant-specific data). The second part of the framework 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, single failure criterion, and appropriate codes and standards. The third part 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 probabilistic (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. In summary, the framework calls for documenting regulatory actions in a logical and orderly fashion.

Since completing the framework document, three major policy issues, of interest to NMSS, have arisen during attempts to implement the framework. Those issues and recommended positions on them are contained in SECY-96-218, October 11, 1996. The first issue concerns the role of performance-based regulation. Without defining performance-based regulation, the recommendation is to, where practical, include performance-based strategies in the

implementation of the risk-informed regulatory decision-making process. The second issue is whether to allow plant-specific applications of safety goals. The recommended position is to develop guidelines for plant-specific decisions that are derived from the Commission's current safety goals and/or subsidiary objectives. (Note the safety goals do not apply to NMSS activities.) The third policy issue of interest is whether risk-informed regulatory decisions should be risk neutral or should they allow increases in risk relative to the current licensing bases. The recommendation to the Commission is to permit increases in risk in some circumstances. A draft of a Staff Requirements Memorandum has been circulating for about two months.

With regard to the possible need to perform a thorough review of the basis for material regulations, DSI 12 states: "In the nuclear materials area, a similar systematic assessment of rules and regulations has not been conducted." (The referenced assessment is that of the Regulatory Review Group effort of 1993 regarding reactor regulations.) However, on March 7, 1995, the Executive Director for Operations (EDO) requested Office Directors and Regional Administrators to identify regulations that are: (1) obsolete, (2) unnecessarily burdensome, (3) too prescriptive, or (4) overlap or duplicate other agencies regulations. As part of that assessment, the Offices were asked to address a series of questions including, "Is it an overly prescriptive regulation? Should it be revised to be more performance-oriented? Can performance be measured?" and "What is the impact on safety if it is eliminated or made less prescriptive?" The direction for the 1995 assessment also included the following guidance: "However, the range of alternatives and recommendations resulting from this review can be broader

than the (Regulatory Review Group) effort." The Director of NMSS responded to the EDO on April 17, 1995, with a report of about 80 pages. Thus, an argument could be made that the April 1995 report is, or goes a long way toward, a response to the possible request associated with DSI 12 for a thorough review of the basis for nuclear materials regulations.

DEFINITIONS

There is value in establishing a common understanding of what is meant by "risk-informed, performance-based regulation." Traditionally, the Commission has recognized that reliance for safety should not be placed on any single element of design, construction, operation, maintenance, training or other activity associated with a license. The current regulations are generally deterministic (with elements of performance) and were constructed around the concept of defense-in-depth. The deterministic approach to regulation considers a set of challenges to safety and specifies how those challenges should be mitigated through regulatory requirements. There are implied elements of probability in that very improbable events need not be considered in making the safety determination. The risk-informed approach can be used to focus deterministic regulations by considering risk in a more coherent and comprehensive manner. By considering risk insights, making use of experience, and using expert judgment, NRC and its licensees can focus regulatory approaches and license activities on those areas of most importance to public health and safety. Where appropriate, a risk-informed regulatory approach can be used to reduce unnecessary conservatism in deterministic approaches or can be used to identify areas with insufficient conservatism and provide the basis for additional requirements.

A performance-based regulatory approach requires at least four key elements:

1. There are measurable parameters to monitor acceptable facility and licensee performance,
2. Objective performance criteria are established to assess performance,
3. There is licensee flexibility to determine how to meet established performance criteria, and
4. Failure to meet a performance criterion must not result in unacceptable consequences.

In theory, a performance-based approach can be implemented without the use of risk insights but would be based on deterministic analyses and performance history.

Risk-informed, performance-based approaches use risk-insights together with deterministic analyses and performance history to develop measurable parameters for monitoring facility and licensee performance, as well as for developing criteria for determining performance, and focus on the results as the primary means of regulatory oversight. In addition, this approach can further focus the regulatory program by defining the goal or purpose of the regulatory action in terms of performance characteristics and safety significance while permitting the licensee flexibility in meeting the regulation. (The reference for these definitions is DSI 12, which is largely based on reactor program activities associated with the PRA Implementation Plan.)

Manual Chapter 0610 on performance-based inspections focuses on issues of safety and reliability with an emphasis on field observation rather than in-office procedural or records review. These inspections tend to focus more on results than on process and method.

On October 4, 1996, the Office of the Inspector General (OIG) transmitted to the EDO their special evaluation entitled, "Better Definition and Planning Needed to Guide NRC's Transition to a Risk-Informed, Performance-Based Regulatory System." Therein, the OIG concluded: "...the agency needs to define what a performance-based system is and how it will affect the citing of violations and the use of enforcement actions." The EDO has yet to respond.

Current Use of Risk-Assessment in NMSS

Health and safety regulation in and of itself entails risk-informed regulation although not necessarily coherent regulation. The overarching Part 20 establishes limits on allowable doses (which can be converted to risk) but contains performance elements (e.g., secure radioactive materials from unauthorized removal) as well as prescriptive requirements (e.g., maintain detailed radiation exposure records.) The nature of the licenses within NMSS are reflective of risk. Very low quantities of byproduct materials are exempt from regulation. Low risk devices can be under a general license with little NRC oversight, while higher risk devices are subject to a specific license and inspections. In general, the inspection (in both frequency and intensity) of NMSS licensees is based on qualitative risk considerations.

The trend within NMSS is toward more risk-informed, performance-based

regulations. However, because of the diversity of nuclear materials applications, the degree of applying this regulatory approach should be different for different regulatory activities. In order to understand this trend, the Divisions and SFPO prepared characterizations on Parts 30 through 40, 60, 61, 70-72, and 76 in terms of the extent to which they are deterministic, prescriptive, risk-informed, or performance-based. Those characterizations are attached. In summary, Parts 30 through 39 are generally deterministic-based with some risk-informed enhancements to Parts 34, 36, and 39. Parts 30 through 39 themselves include a mix of prescriptive and performance-based regulations. However, the Regulatory Guides, Inspection Procedures, and licensing practices associated with those parts lead to implementation of a regulatory program which is more prescriptive than performance-based.

The Division of Industrial and Medical Nuclear Safety (IMNS) is undertaking an extensive project to update and consolidate all existing Division 10 Regulatory Guides (General), Policy and Guidance Directives and Standard Review Plans, concerning material uses. To the maximum extent possible, the existing licensing guidance documents will be consolidated into NUREGS, containing both application and review information in one document for use by the regulated community and NRC reviewers. For those existing documents not readily lending themselves to consolidation, they will be updated. In addition to making the guidance documents "user friendly," the degree of prescriptiveness applied to the documents will be consistent with the degree of risk associated with the use of byproduct material being addressed. The risk-informed, performance-oriented concept will be applied to the extent

possible. For example, industrial radiography guidance will be rather prescriptive compared to guidance associated with the use of gas chromatography, etc. As another example, IMNS recently issued a draft NUREG that takes a graded, more performance-based approach to licensing portable gauges, and reduces the information needed in support of an application.

On June 20, 1995, the Commission approved a staff plan to form a Working Group (WG) to evaluate current regulations on general- and specific-licensed devices. The formation of the WG was necessary to address the apparent inadequate licensee control of devices that has led to radioactive materials being included in metal scrap intended for recycling. The task of the WG was to assess the current regulatory programs for general- and specific-licensed devices and suggest a baseline for regulating these devices. The WG completed its evaluation and submitted recommendations to NRC on July 2, 1996. The major recommendation of the WG was to implement a program for increased oversight of certain devices under either specific or general licenses.

On November 13, 1996, the WG and NMSS staff briefed the Commission on the WG's recommendations and the staff's proposed actions. Specifically, the staff proposed to complete its evaluation of the WG's recommendations and to provide an action plan for the recommendations the staff plans to implement and justification for those that it will not. The Commission approved the development of the action plan in a Staff Requirements Memorandum dated December 31 1996. The action plan is due to the Director of NMSS March 28, 1997.

Over the past decade, the staff has attempted, through its contractors, to quantify the risks associated with unaccounted-for devices with limited success. In May 1995, the staff initiated an in-house risk assessment that employs the methodology currently used for reactor PRAs. The assessment includes establishing the probabilities of devices being lost, causing exposure to members of the public, entering the metals manufacturing stream, being smelted and other incidents. The scope of the assessment comprises only industrial devices containing cesium-137 or cobalt-60, because of the relatively higher risk of these devices to health, safety, property, and the environment, and because these types of devices pose the highest threat to the scrap recycling and steel making industries. The risk assessment is to be completed in September 1998. Once complete, the staff will evaluate the methodology to determine whether it can be used to develop similar risk assessments for other types of devices.

Some of the requirements in Part 40 concerning the disposition of uranium mill tailings are performance-oriented, but most of Part 40 is prescriptive. Some licensees have argued that aspects of uranium mill tailings regulations are unnecessarily burdensome, overly prescriptive, and are not warranted on costs and benefits. NMSS has adopted a new performanced-based licensing approach for uranium recovery facilities which provides licensees more flexibility in the way they meet the conditions of their licenses, and allows licensees to make changes to their facilities or operations, under certain conditions, without involving the NRC.

Part 60 contains elements of deterministic, prescriptive, risk-informed, and

performance-oriented requirements. Part 60 is deterministic in that, for example, it requires: (1) substantially complete containment of high-level wastes (HLW) within the waste packages for specific periods of time, (2) a limit on the fractional release rate from the engineered barrier system, and (3) a limit on groundwater travel time. It is prescriptive in many areas (e.g., favorable conditions, potentially adverse conditions, and quality assurance.) Part 60 requires conformance to the Environmental Protection Agency's (EPA) generally applicable environmental standards for HLW repositories. That standard is clearly risk-informed, since the primary measure for postclosure performance is a probabilistically derived quantity representing cumulative radionuclide releases to the accessible environment over 10,000 years, weighted by factors for each radionuclide representative of the nuclide. Since the repository must perform in specified ways far into the future, Part 60 is performance-oriented (the performance can not be measured but must be calculated). Some have criticized Part 60 as being way too prescriptive. Part 60 must be modified either because of the Energy Policy Act of 1992, or because of possible legislation pending before Congress. The issue of how risk-informed, performance-based that revision should be can be addressed in any such rulemaking.

Like Part 60, Part 61 has deterministic, prescriptive, risk-informed, and performance-oriented provisions. It provides performance objectives and is a system-based rule. The technical requirements, which are more prescriptive, are directed at ensuring that the performance objectives will be satisfied. However, the rule allows flexibility in departing from the technical requirements provided the performance objectives are satisfied. Protection of

the general population has a stated deterministic limit for doses to an individual; since the performance measure is dose, this requirement is, in a sense, risk-informed.

Operators of fuel cycle facilities are licensed to possess special nuclear material under Part 70, which has requirements that are prescriptive (e.g., alarm points for criticality monitors), performance-based (e.g., construction of a facility must protect against natural phenomena), risk-informed (e.g., an emergency plan is required if credible releases of radioactive material result in doses to the public in excess of specified levels), and deterministic (e.g., redundancy of criticality monitors). The Division of Fuel Cycle Safety and Safeguards encourages licensees to voluntarily perform an Integrated Safety Analysis (ISA) to identify the hazards at their facility, analyze how those hazards could result in accidents, and identify those aspects relied upon to prevent or mitigate the accidents. For some facilities, qualitative methods are cost-effective; for high-risk facilities, or for high-risk systems within otherwise low-risk facilities, qualitative methods could be supplemented by quantitative methods if necessary data are available. On September 30, 1996, the Nuclear Energy Institute (NEI) submitted a petition to amend Part 70 by requiring uranium processing, enrichment, and fuel fabrication licensees to utilize either an ISA, or an acceptable alternative approach to confirm that adequate controls are in place to protect public health and safety. (The Federal Register Notice of receipt of the petition was published on November 26, 1996, with the comment period ending on February 10, 1997. The staff will evaluate those comments and develop a position on the petition.)

The regulations of Part 71 are mostly prescriptive and deterministic. Complications arise in implementing changes to Part 71 because of the impact changes would have on the international community and other federal regulatory bodies. NRC has sponsored PRA's of transportation of radioactive materials, the results of which show that Part 71 provides adequate protection of public health and safety. The current SPFO/NMSS position is to base future changes to Part 71 on risk-informed, performance-based criteria. An example of this would be the addition of the Type C package that was recently added to the International Atomic Energy Agency (IAEA) regulations for air shipment of large quantities of radioactive material. The new requirement emphasizes risk-informed, performance-based criteria.

The regulations under Part 72 are generally based on deterministic considerations. An example of the deterministic format is in Section 72.90(d) which states: "Proposed sites with design bases external events for which adequate protection cannot be provided through (Independent Spent Fuel Storage Installation) or (Monitored Retrievable Storage Installation) design shall be deemed unsuitable for the location of the ISFSI or MRS." The extent to which Part 72 could be changed to reflect a more risk-informed, performance-based format is limited by the directive of Section 218(a) of the Nuclear Waste Policy Act of 1982, which states: "...The Secretary (of DOE) shall establish a demonstration program in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the (Nuclear Regulatory) Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need

for additional site specific approvals by the Commission."

The staff of the SFPO has outlined an approach to applying PRA techniques to dry cask storage systems. The approach consists of a pilot PRA study of one dry storage system design at one site and would entail the following:

- An analysis to identify and characterize the cask(s) and fuel damage that would be required to occur in order to reach the accident dose limits in 10 CFR 72.106(b).
- A comprehensive analysis to identify potential sequences that could lead to the consequences identified above.
- For sequences identified, a probabilistic analysis to determine the likelihood of the sequences.

The results of this study would potentially be used to support the adequacy of the existing dry storage system designs, procedures, and regulations. The results would also be used to make recommendations as to the extent to which an expansion of PRA methods for dry cask storage would provide further useful information. The staff estimates that the pilot PRA study would require approximately 1.8 FTE of contractor assistance personnel, which would cost approximately $275,000. The estimate does not include the NRC staff time that would be necessary to direct and oversee the project. There is no money budgeted for this effort.

Part 76 contains requirements that are prescriptive, performance-based, risk-informed and deterministic. For example, licensees must provide, in each

appropriate area, two criticality monitors, consistent with defense-in-depth philosophy. Section 76.35 has a performance-based character in requiring descriptions of equipment and management controls that are necessary to protect health and safety. The criticality monitor requirements have a risk-informed component in that they must be capable of detecting prescribed dose levels. The requirement to assess accidents is an example of deterministic regulation

Public Comments on DSI 12

The Strategic Assessment team has summarized, for the Commission, all of the public comments. Following are highlights of the approximately 20 comment letters received that addressed the materials aspect of DSI 12. NEI believes the option to implement a risk-informed, performance-based approach to satisfying the regulations should apply to all licensees, with the specific methods of application tailored to the circumstance (e.g., hazards analyses as opposed to PRA's). Mallinckrodt had the same comment and added that they believe medical licensees, manufacturers, and the research community all have serious concerns that many NRC regulations are unnecessarily prescriptive and should be subjected to a comprehensive review. Mallinckrodt also believes PRA methods for nuclear materials and medical programs should be established prior to adopting the risk-informed, performance-based regulatory approach. Finally, they believe there should be a radiation standard setting agency (not EPA or NRC). The Council on Radionuclides and Radiopharmaceuticals echoed Mallinckrodt (or vice versa).

The Organization of Agreement Statements (OAS) and the Conference of Radiation Control Program Directors (CRCPD) noted that DSI 12 failed to discuss the impact of compatibility determinations by NRC on regulations it promulgates. OAS expressed the concern that risk and cost/benefit analyses require assumptions to be made that may not be applicable to specific Agreement States circumstances, creating a significant conflict. The Pennsylvania Department of Environmental Protection submitted a 67 page paper entitled, "A Risk Based Methodology for Assessing the Efficacy and Priorities of Radiation Protection Programs." The State of Illinois urged use of the Safety Goals.

The Non-Destructive Testing Management Association believes it is imperative that the NRC define objective safety goals for the radiography industry in general and for new proposed rules in particular. Objective goals would highlight the need for NRC to collect reliable and relevant radiography safety data. They believe the majority of the major safety violations in the industry are committed by only a few radiographers, leading to new regulations that are not helpful but costly to the many.

The National Mining Association called for a thorough review of the regulations from a risk-informed, performance-based perspective.

The Environmental Coalition on Nuclear Power and Public Citizen's Critical Mass Energy Project were opposed to a risk-informed, performance-based regulatory regime on the grounds that such an approach would lead to an erosion of safety margins.

The Advisory Committee on the Medical Uses of Isotopes agreed that risk should be a factor in establishing regulations, but made a number of comments on the medical use program.

The Department of Energy (Office of Civilian Radioactive Waste Management) supported streamlining Part 60 and making it risk-informed, performance-based.

In commenting on DSI 12 as it relates to nuclear reactors, NRC's Director of Enforcement expressed concern about the emphasis on risk-based regulations as well as on performance-based approaches, likening it to the no-harm, no-foul theory. He believes performance-based regulation works best in well financed industries.

Discussion

Most of the commentors on DSI 12 favored moving toward a risk-informed, performance-based approach in regulating radioactive materials as long as there is a recognition that it should only be done if cost effective. The commentors noted that, because of the diversity of activities regulated within NMSS, there would need to be differing approaches taken, depending on the nature of the circumstances. Issues raised are: is there a need for a safety goal in the materials area, is there an adequate methodology for performing risk assessments, how will enforcement be carried out, and what is meant by performance-based regulation.

The framework for risk-informed, performance-based regulation developed for nuclear reactor regulation is not onerous. It brings a logical structure to

the decision-making process, moves the program toward coherency, offers the potential for greater focus of NRC and licensee activities, and preserves the traditional defense-in-depth philosophy.