POLICY ISSUE
NOTATION VOTE

October 7, 2004 SECY-04-0182

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

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

PURPOSE:

To provide a progress report on the systematic process being developed for risk-informing regulation in the Office of Nuclear Material Safety and Safeguards (NMSS), to describe the staff's plan to use the proposed approach on selected NMSS activities, and request approval to discontinue this report.

BACKGROUND:

The staff proposed an approach to risk-inform NMSS regulatory activities in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999. This approach was designed to: 1) focus Agency and licensee resources on areas commensurate with their importance to safety; 2) provide a framework for using risk information; and 3) where amenable, use risk information to provide flexibility for making decisions and managing the workload in NMSS more effectively. The framework defined the potential areas where risk-informing can play a role in the regulation of NMSS activities and, as part of its implementation, the staff proposed to develop risk metrics

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and goals to help guide the risk-informed activities. In a Staff Requirements Memorandum (SRM) dated June 28, 1999, the Commission approved the staff's proposal in SECY-99-100 to develop risk metrics and goals and to address risk management practices consistent with other Agency policies.

On June 24, 2003, the staff provided the Commission with a status of risk-informed regulation in NMSS activities in SECY-03-0126, "Risk-Informed Regulation for the Office of Nuclear Material Safety and Safeguards: Status Report and Plan for Future Work." This update described: 1) examples of areas where the staff has successfully used a risk-informed approach to improve effectiveness and efficiency; 2) the development of guidance documents to help the staff consistently and effectively apply a risk-informed approach; and 3) plans for continuing to risk-inform NMSS activities. In an SRM dated October 22, 2003, the Commission approved the staff's plans to continue advancements in risk-informing its regulatory activities and directed the staff to provide the Commission with biannual reports on the progress made in developing risk metrics, tools, data, and guidance for implementing risk-informed approaches for the materials and waste arenas.

The staff partially responded to SRM-SECY-03-0126 by providing a memorandum to the Commission, on July 9, 2004, that described the status of the ongoing risk-informed activities in NMSS. The memorandum informed the Commission that NMSS plans to transition from the development of a systematic risk-informing approach to the implementation of such an approach on a case-by-case basis. Because essentially all resources in NMSS in the upcoming years are obligated for programmatic activities, the Risk Task Group (RTG), which has led this development of a systematic risk-informing framework, was phased out at the end of fiscal year (FY) 2004. The application of the systematic risk-informing approach will be carried out by the NMSS divisions, as appropriate, and within the available resources.

DISCUSSION:

Risk-informing is a powerful tool to plan for NMSS programmatic activities and to leverage available resources to complete the planned activities while accommodating emergent work. As directed by the Commission in SRM-SECY-99-100 and SRM-SECY-03-0126, NMSS continues to expand the use of risk information to regulate activities in the material and waste arenas. Additionally, NMSS has developed a systematic risk-informing process and some of the associated preliminary decision considerations that integrates the consideration of different types of health impacts with other factors involved in risk-informed decision-making.

The proposed systematic risk-informed process, which has been developed in cooperation with the Office of Nuclear Regulatory Research (RES), contains the following four major steps:

1. Clearly define the regulatory issue and any preliminary alternative action(s);
2. Decide whether to risk-inform;
3. If a risk-informed approach is to be used, perform a risk assessment as needed; and
4. Apply risk-informed decision method

A summary of this proposed four-step risk-informing decision-making process is provided in Attachment 1.

The proposed approach, including specific decision methods, have been documented in a draft guidance report for use by NMSS staff and not for public release until it is finalized. The purpose of the guidance document is to provide a structured framework that integrates the consideration of risk with other factors to facilitate staff's use of risk insights in making decisions. Because each activity involves a range of potential radiation impacts, including routine doses, chronic exposures, and potential accident risk, risk insights for each of these potential impacts can contribute to decision making. This document provides guidance to staff as to how such risk insights can be considered. The draft approach for risk-informing is neither a regulatory requirement, nor does it replace existing guidance for regulating nuclear material and waste activities. This method is meant to be a supplementary tool to guide staff in risk-informing decisions. In addition, the draft guidance document, while useful in its present form, is continually being improved upon. It may require modification or the addition of new criteria, some of them adapted to particular needs or application areas. It is intended to be a living document incorporating the lessons learned as NMSS continues to risk-inform specific activities.

NMSS and RES staff, the NMSS Risk Steering Group, and the members of the Advisory Committee on Nuclear Waste (ACNW) have reviewed and provided comments on the key features of the proposed risk-informed process. Comments from these groups have been considered and incorporated into the current draft of the guidance report. The next step is to apply the proposed systematic approach documented in the draft guidance report on a case-by-case basis. The application of the proposed process to NMSS-regulated activities will provide an opportunity for the staff to learn, critique, and suggest possible improvement of the systematic process and will facilitate staff's acceptance of the risk-informed approach. In addition, results from a working group and pilot studies that evaluated the proposed process, demonstrated that the use of a systematic risk-informed approach would lead to more transparent decisions and achieve resource savings while maintaining or improving safety (see Attachment 2 on the potential resource savings). It is expected that similar results will be obtained in future applications of the systematic risk-informed approach.

Since separate funding has not been allocated for risk-informing NMSS activities, starting in FY 2005 and beyond, staff will identify those ongoing and emerging activities that are feasible and beneficial by using the screening process in Step 2 of the process. These selected NMSS activities may include licensing casework, inspection, rulemaking, and guidance and developmental work. If public interactions are part of those routine programmatic activities, NMSS will use this opportunity to obtain public feedback on the proposed process.

RES will continue to provide assistance on performing realistic risk calculations, such as data collection and interpretation, modeling approaches, and analysis. RES will also assist in revising and updating the draft risk-informed guidance to reflect lessons learned, as resources permit. Furthermore, RES will assist in addressing recommendations from the June 9, 2004, ACNW letter, such as defining the quality of nuclear material risk assessments, as more knowledge and experience on NMSS risk assessments become available.

In addition, a communication plan has been developed for outreach so that the NMSS management, the staff, and other offices have a clear understanding of NMSS' goals, desired outcomes, and plans for continuing the risk-informed effort.

RESOURCES:

As a result of the FY 2006 Planning, Budgeting, and Performance Management process, NMSS concluded that it is necessary to make resources that had been allocated to RTG to other, higher-priority work, including emerging casework. Funding for the RTG in FY 2004 was $400K and 4 FTE and is discontinued after FY 2004. NMSS will continue its commitment to risk-inform activities through integrating that focus into its day-to-day operations and carrying out these activities in individual programs that are budgeted. RES' budgeted resources to provide assistance for this effort decline from $100K and 0.8 FTE in FY 2005 to $0K and 0.8 FTE in FY 2006. Any subsequent program modifications will be implemented through the normal budget process.

CONCLUSION:

A systematic risk-informing framework has been developed in NMSS to improve regulatory activities, enhance safety, and perform work in a more effective and efficient way. The staff plans to continue expanding the use of risk-informed methods on materials and waste regulatory activities. The next step is the application of the proposed process, on a case-by-case basis, to resolve key safety and security issues, to inform and involve stakeholders, and to gain insights to ensure that staff's actions are effective, efficient, realistic, and timely. The staff will continue to keep the Commission informed of ongoing activities through the Risk-Informed Regulation Implementation Plan updates.

COORDINATION:

The Office of the General Counsel has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

/RA/

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for Operations

Attachments:
1. Overview of a Framework for Risk-Informed Decision-Making in NMSS
2. Potential Resource Savings by Using a Systematic Risk-Informing Process

OVERVIEW OF A FRAMEWORK FOR RISK-INFORMED DECISION-MAKING IN NMSS

Risk-informed decision-making uses risk insights, along with other important information, to assist in making decisions. Because there are many factors to consider (such as security, defense-in-depth, safety margins, and cost), using a structured process can facilitate in making transparent, comprehensive, and consistent risk-informed decisions. This attachment describes a proposed structured framework to risk-inform decisions in the materials and waste arenas.

The proposed process consists of four major steps:

Step 1. Clearly define the regulatory issue and preliminary alternative actions
Step 2. Decide whether to risk-inform
Step 3. If a risk-informed approach is to be used, perform a risk assessment as needed
Step 4. Apply risk-informed decision method

The four-step process is illustrated in Figure 1-A. Although the process is shown as a simple single-pass sequence of steps, in practice, it is an iterative process that is expected to be carried out as a coordinated team effort involving a number of disciplines and responsibilities. The staff having responsibility for the regulatory area where the issue resides should be substantially involved in Steps 1 and 2. The third and fourth steps often require assistance from risk analysts. A more detailed discussion of each of the four steps follows. The reason for this four step approach is that, unlike the reactor arena, a variability exists in the feasibility and usefulness of risk-informed regulation in material and waste programs. Hence risk-informing should be pursued in a manner adapted to each activity.

STEP 1: CLEARLY DEFINE THE REGULATORY ISSUE AND PRELIMINARY ALTERNATIVE ACTIONS.

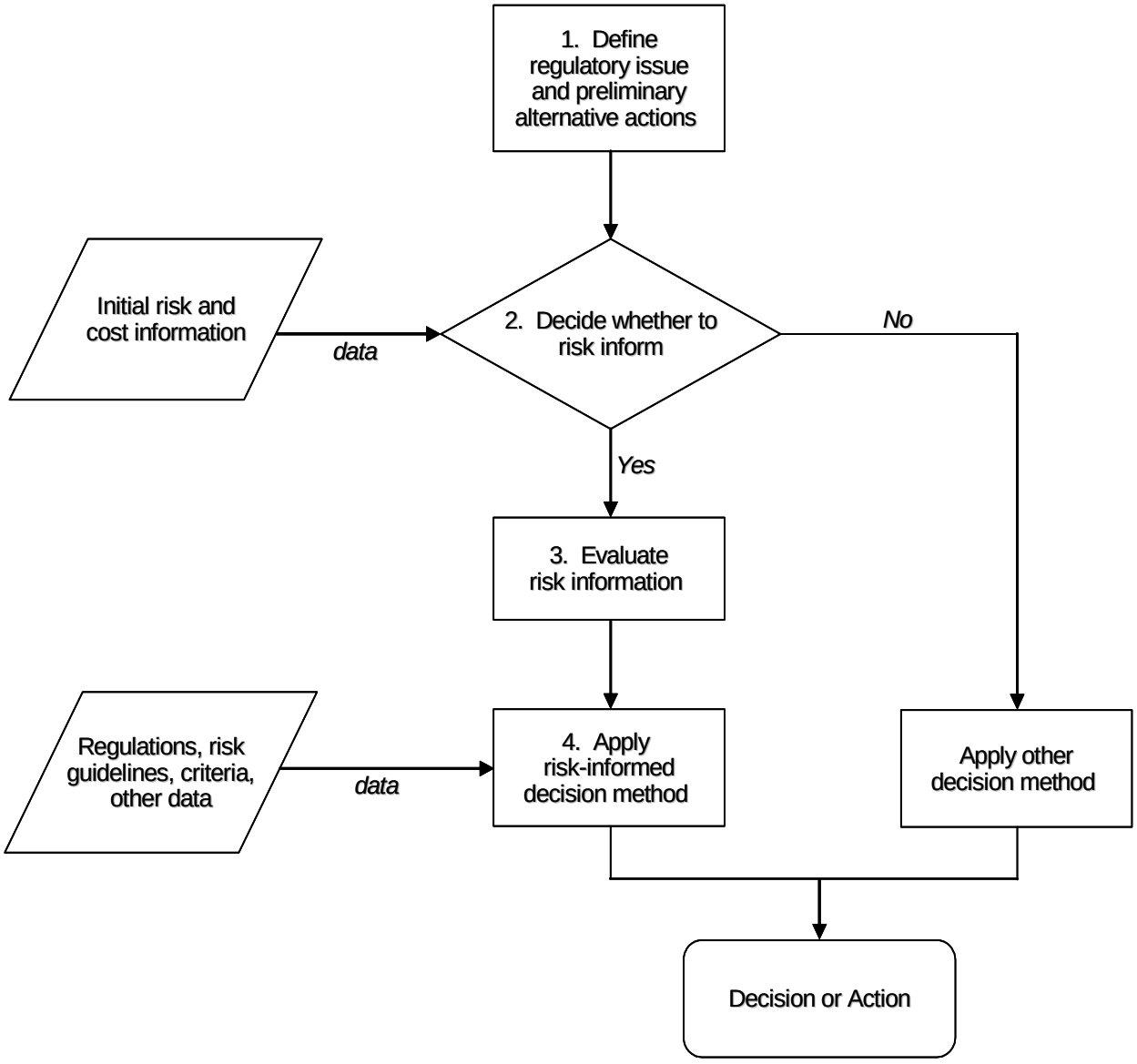
The first step in any decision-making process is to clearly define the issue or question; that is, what is the concern and how might risk information help resolve it. After defining the issue, one or more actions that might resolve the issue should be proposed. Two common alternative actions may be to impose a new safety requirement to reduce risk, or to grant an exemption or change to an existing requirement, where the concern is that risk may increase. It is typically useful to formulate a number of proposed alternative changes which can be evaluated (in Step 4 below) to determine which appears to be most effective.

STEP 2: DECIDE WHETHER TO RISK-INFORM.

After the issue has been defined and preliminary alternative actions have been identified, the next step is to review against a set of four screening considerations to determine if the choice among the alternatives should be risk-informed. Table 1-A lists these screening considerations. The first screening consideration determines whether risk information would be useful in a decision process supporting one of the Commission's strategic goals of safety, security, openness, effectiveness, and management excellence. These considerations are closely related to Step 1, that is, defining the issue and objective. If risk insights will not inform the decision process, then a risk-informed approach need not be pursued. The last three considerations ask whether developing and using the risk information is feasible, cost-effective, and not precluded by other considerations such as legal or policy constraints. The purpose of

using these screening considerations is to ensure that risk-informing is used in a cost-effective manner and is focused on the agency's strategic goals.

Figure 1-A. Overall Risk-Informed Decision-Making Process Diagram



STEP 3: PERFORM RISK ASSESSMENT AS NEEDED.

The third step is to develop or compile the necessary risk information to support a risk-informed decision. The initial task is to determine the scope of the risk assessment. The analyst needs to identify the risk metrics that need to be calculated, and the level of quality and detail needed in the risk assessment. This step does not necessarily require performing a large-scale complex probabilistic risk analysis. In some cases, risk information may already be available. In other cases, a simple risk analysis may be sufficient to yield the appropriate level of risk information. The degree of completeness, applicability, detail, and robustness in the risk assessment should be commensurate with the type of decision to be made.

It is usually important to include the uncertainty in the risk assessment results, either quantitatively or qualitatively. This information can be used in Step 4 to evaluate the robustness of the risk information in making a risk-informed decision.

Table 1-A. Screening Considerations

BENEFITS OF A RISK-INFORMED REGULATORY APPROACH

(1) Could a risk-informed regulatory approach help address one or more of the goals in the Commission's Strategic Plan? (safety, security, openness, effectiveness, management excellence)

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

FEASIBILITY OF IMPLEMENTING A RISK-INFORMED APPROACH

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

If the answer to consideration 2 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

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

If the answer to consideration 3 is yes, proceed to next consideration; if not, the activity is considered to be screened out.

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

If the answer to consideration 4 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or be screened out.

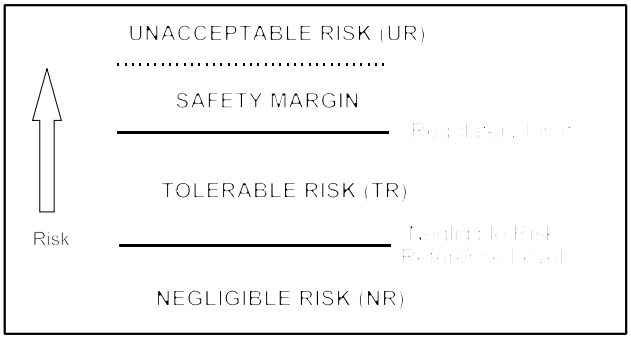
STEP 4: APPLY RISK-INFORMED DECISION-METHOD.

In this step, the risk insights developed in Step 3 are used, together with other pertinent considerations, in an integrated manner to facilitate decision-making. This decision process is structured to assure that factors known to affect regulatory decisions are given proper consideration. The factors considered in this step include risk to individual workers and the public from both routine and accidental exposures, defense-in-depth, safety margins, security, cost impacts, and others as indicated in guidance on regulatory analysis. Some of these factors are considered quantitatively, such as routine and accidental exposures, while others can only be judged qualitatively.

Consideration of the risk to individuals is based on a concept of three regions of risk to individuals. This conceptual framework is shown in Figure 1-B. The framework embodies three concepts:

1) If a proposed action results in risk to individuals that is judged to be too high, this may be sufficient grounds to reject it.
2) If the resulting level of risk to individuals is in the tolerable region (and other factors are adequately addressed), then alternative actions should be preferred based on highest net cost-benefit.
3) Proposed new requirements to lower risk, when it is already in the negligible risk region should normally not be pursued.

Figure 1-B. Three-Region Risk Diagram



The three-region risk diagram is a conceptual representation of decision considerations involving individual risk. Both in theory and practice, the “lines” separating these regions are not unique and precise. In particular, in considering whether individual risk is too high (in the unacceptable region), uncertainties must be taken into account. In practice, the uncertainty is often managed by specifying a limit value that incorporates margin, by prescribing a conservative method of analyzing the risk against it, or by requiring multiple diverse preventive and mitigative measures to be in place. Thus, the practical methods chosen to implement the 3-region concept may be considerably more complex than this simple diagram.

Both routine exposure and unanticipated events should be considered in risk-informed decisions. Routine exposure is dealt with quantitatively in 10 CFR Part 20, which prescribes what is unacceptable from a regulatory standpoint, including public and worker annual dose

limits. The annual dose limits in 10 CFR Part 20 can be used as a risk-informing tool to assure that proposed regulatory actions make sense in terms of keeping individual routine dose in the tolerable region of the three-region diagram.

The principles embodied in the three-region decision framework can also be applied to managing unanticipated events. This risk involves both the frequency or probability of occurrence for each scenario, as well as the dose that would occur. Since there are typically multiple possible scenarios, risk is the sum over all scenarios of the product of frequency, dose, and probability of fatality given that dose. Thus, in the three-region framework, risk is typically expressed as frequency of fatality. Unlike the situation for routine doses under 10 CFR Part 20, unanticipated event risk limits appear only occasionally in the regulations. The Commission has not ascribed generally applicable numerical limits on this type of risk. However, limiting the risk to a tolerable level is one factor to be considered, along with others, in evaluating public safety on a case-by-case basis.

The negligible level of risk is useful as a screening tool when new regulatory requirements are to be imposed for the purpose of reducing risk. If the risk is already in the tolerable region or below, and the proposed new requirement would reduce it by an amount that is negligible, then the new regulatory requirement is unlikely to be cost-effective, and should not be pursued. Negligible risk levels are well below the limit levels of risk, and represent an insignificant addition relative to average normal risks.

POTENTIAL RESOURCE SAVINGS
BY USING A SYSTEMATIC RISK-INFORMING PROCESS

From 2000 - 2001, a Task Group examined the nuclear byproduct materials inspection program using a risk-informed approach and made recommendations to revise the byproduct materials Inspection Program. Separately in 2003, two pilot studies were conducted to test the proposed systematic risk-informing process. This attachment describes the broad perspective gained on the effectiveness of the risk-informing process and insights on cost savings resulting from this process.

2A. MALLINCKRODT PHASE II LESSONS LEARNED - IMPROVING THE NUCLEAR BYPRODUCT MATERIALS INSPECTIONS PROGRAM

From the Fall of 2000 to the Summer of 2001, a U.S. Nuclear Regulatory Commission (NRC) Task Group evaluated the nuclear byproduct materials inspection program to determine if programmatic changes were warranted to improve efficiency and effectiveness while maintaining safety. This evaluation included: the use of risk insights from detailed analysis of NUREG/CR-6642, *Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Systems and its Associated Byproduct Materials Risk Database*; an evaluation of the current program and operational data, including inspection scheduling data, historical enforcement data, and event-related data; and applications of risk insights to improve the existing inspection program.

NUREG/CR-6642 provides a method for ranking byproduct material systems according to potential risk. The study evaluated various scenarios that might result in unintended doses for workers or members of the public and their respective probabilities of occurrence. In an effort to focus the Task Group's use of this byproduct materials risk information on risk-significant activities, a systematic approach was used. Consequence bins of interest were developed assuming that certain consequences, if they occurred, would be highly unacceptable to NRC and would result in the expenditure of significant inspection resources. As such, routine inspections that focused on lowering the probability of the occurrence events with unacceptable consequences would be cost-beneficial while maintaining or improving safety. Specific dose reference levels were chosen to correspond to these consequence bins of interest, such as exposures exceeding regulatory dose limits and doses in the lethal and sub-lethal ranges. Also, a set of probability ranges was proposed, for each of these consequence bins of interest, that was commensurate with the level of risk significance of the respective consequence to help focus the review effort.

The Task Group used this framework to gain insights on which aspects of a licensee's program should receive the greatest attention during an inspection. Specifically, the byproduct materials risk data were analyzed to identify two characteristics: 1) the maximum potential dose resulting from any of the scenarios identified and analyzed for each of the systems; and 2) underlying types of program failures that could lead to the scenarios described in NUREG/CR-6642.

Based on this review, the Task Group concluded that the byproduct materials risk data supported the current inspection model regarding which programs should receive greater inspection attention. In evaluating the second characteristics--types of program failures--the Task Group noted that there were relatively few different types of failures and that several of the failure types were common to multiple scenarios. The Task Group used the results of this analysis, in combination with work completed in support of prior inspection procedure modifications, to develop a model for establishing generic and program-specific performance elements that could serve as cornerstones for conducting a risk-informed, performance-based inspection for byproduct material licensees. As a result of the effort, the number of routine inspections has been reduced by more than 20 percent and has led to procedures that better focus on licensee performance in key areas.

2B. REGULATION OF CHEMICAL AGENT DETECTORS/CHEMICAL AGENT MONITORS

This is one of the two pilot studies conducted in 2003 to test the proposed systematic risk-informing process. The Department of the Army is the holder of a Byproduct Material License issued by NRC pursuant to 10 CFR Part 30, which authorizes possession and use of chemical agent detectors containing small amounts of americium-241 or nickel-63. These detectors are used by soldiers in the field to detect chemical warfare agents so that protective measures can be appropriately taken. The Army possesses approximately 60,000 of these detectors. Between June 2001 and November 2002, it reported losing 19 chemical agent detectors domestically and overseas. These devices are used in wartime and simulated battlefield conditions. Because of the conflict in Iraq and elsewhere in the world, it was projected that the loss of these devices would continue at the same rate or increase. Because of the quantity of americium-241 in some of these detectors, such losses are considered a Severity Level III violation under the NRC Enforcement Policy. A Severity Level III violation normally results in a civil penalty and the consumption of considerable NRC and licensee resources to address the cause and prevention of the violation. However, because of the low dose rate, the fixed form of isotopes, and the locations of their use, loss of these devices may not warrant the Enforcement Severity Level currently specified in the Enforcement Policy.

Using byproduct materials risk information in NUREG/CR-6642, a risk assessment was performed to better quantify the risks associated with the U.S. Armed Services' loss of control and accountability of the chemical agent detectors/chemical agent monitors. The staff performed a risk assessment that specifically modeled the risk represented by the loss of chemical agent detectors/monitors under a less stringent regulatory system and compared it to the risk of the use and loss of these devices assumed under the current regulatory requirements. The risk assessment and the cost-benefit analysis indicated that the risks associated with the loss of these devices do not seem to warrant the current regulatory framework for control of these devices. As a result, the staff proposed several options in providing relief to the enforcement policy. In its Staff Requirements Memorandum on SECY-03-0167 - "Proposed License Amendment and Enforcement Action for the U.S. Military," the Commission directed the staff to grant enforcement discretion regarding the loss of this type of device. The costs associated with the NRC's enforcement actions towards U.S. Armed Services in previous years can be used as an indication of the annual savings from this risk-informed decision.

2C. ACCEPTANCE CRITERIA USED TO CERTIFY SPENT FUEL STORAGE CASKS

This is another pilot study conducted in 2003 to test the proposed systematic risk-informing process. The proposed systematic risk-informing process was retrospectively applied to the issues addressed in the Spent Fuel Project Office's Interim Staff Guidance No. 18, "The Design/Qualification of Final Closure Welds on Austenitic Stainless Steel Canisters as Confinement Boundary for Spent Fuel Storage and Containment Boundary for Spent Fuel Transportation." Specifically, this study focused on conducting confinement reviews for the certification of spent fuel storage at independent spent fuel storage installations.

The proposed regulatory action was the removal of requirements for: 1) the storage cask designers to conduct hypothetical off-site dose consequence calculations that are typically included in safety analysis reports; and 2) licensees to conduct leakage testing on certain types of storage cask designs. The staff believed that there was reasonable assurance that no credible leakage would occur from the final closure welds of an austenitic stainless steel spent fuel storage canister when following the American Society of Mechanical Engineers code requirements. Through the test of the draft guidance document, the staff determined that safety is assured while realizing cost savings.