

## **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.