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**NRC EFFORTS ON REGULATORY APPROACHES
FOR CONTROL OF SOLID MATERIALS**

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ABSTRACT

The U.S. Nuclear Regulatory Commission's (NRC's) regulations that set standards for protection of the public against radiation do not currently contain specific requirements for the control of solid materials with small or no amounts of radioactivity. Absent a National standard, NRC routinely evaluates, on a case-by-case basis, licensee requests to release solid materials when they are obsolete or no longer useful during operations, or when the facility is being shut down during decommissioning. As part of its continuing examination regarding the control of solid materials, NRC sponsored and received a report from the National Academies' (NA's) National Research Council that reviewed technical bases, policies, and precedents, and made several recommendations for moving forward on this issue. NRC evaluated the NA report and developed a set of options for proceeding with a process for examining approaches for control of solid materials. This paper explains the option that NRC chose and summarizes NRC's technical basis development and related National and international activities.

INTRODUCTION

There are currently no generally applicable NRC regulations, in 10 CFR Part 20, for the control of the majority of solid materials containing small or no amounts of radioactivity (1). In the absence of a National standard for the release of solid materials, NRC currently addresses the release of solid material on a case-by-case basis, using license conditions, existing regulatory guidance, or other case-specific criteria (2, 3, 4, 5, 6). In June 1999, NRC published an Issues Paper to solicit public input on its examination of the current approach for control of solid material, which included the following alternative courses of action: (a) continue current practice (i.e., no rulemaking); (b) establish a new standard to permit release of material for unrestricted use, based on dose levels; (c) establish a new standard that prohibits release of material that had been in an area in a licensed facility where radioactive material was used or stored; and (d) establish a new standard that restricts release to only certain authorized uses (7).

Solicitation of public input on this issue was successfully obtained, using various forums, including the establishment of a dedicated website for this activity, a series of public meetings throughout the United States, and written comments in response to publication of the Issues Paper. Various stakeholders sent NRC more than 800 comments on this topic, which NRC staff discussed, in a paper sent to the Commission (SECY-00-0070) and subsequently published in report NUREG-/CR-6682 (8, 9). In May 2000, the Commission held two open meetings on the contents and recommendations in SECY-00-070 and obtained the views of representatives from stakeholder groups. In summary, stakeholder views were diverse, ranging from opposition to releases of radioactivity that could end up in consumer products, to general support for the establishment of a National standard for unrestricted release of solid materials.

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Many commenters indicated that restricted use, also referred to as conditional clearance or authorized use, had merit as a means of keeping solid materials out of consumer use. However, there were concerns about whether a large-scale restriction on recycled solid material in the public sector would be practicable. An additional alternative identified was requirements for segregating solid materials, which would entail different release strategies for different types of solid materials.

NA'S STUDY ON THE CONTROL OF SOLID MATERIAL

In August 2000, the Commission decided to defer a final decision on whether to conduct a rulemaking on this issue and directed the staff to proceed with an NA study on possible alternatives for the control of solid materials (10). The NA began the study in August 2000 and held information-gathering meetings with stakeholder groups throughout 2001. In March 2002, NA issued findings and recommendations in a final report entitled, "The Disposition Dilemma: Controlling the Release of Solid Materials from Nuclear Regulatory Commission-Licensed Facilities" (11). The NA report discusses the existing regulatory framework for control of solid materials, stakeholder reactions, anticipated inventories, dose analysis methods, costs measurement issues, international approaches, and other considerations related to this issue. The NA report focuses on two overarching findings and seven recommendations, supplemented with 31 specific findings.

NRC staff reviewed the NA report based on the four performance goals of NRC's Strategic Plan (12), which are: (1) maintain safety, protection of the environment, and the common defense and security; (2) increase public confidence; (3) make NRC's activities and decisions more effective, efficient and realistic; and (4) reduce unnecessary regulatory burden on stakeholders, both licensees and other affected industries. The following briefly summarizes the overarching findings and recommendations contained in the NA report, along with the results of the NRC staff's review.

Overarching Findings of the NA Report and NRC Staff Review

The first finding is that NRC's current approach on control of solid materials is workable and sufficiently protective of public health and safety and does not need immediate revamping. However, the NA report notes that the current approach is not explicitly risk-based, that there are inconsistencies in its application, and that it lacks guidelines for volume-contaminated material. Based on these limitations, the NA report recommends that NRC should begin a process of evaluating alternatives to the current system. The second finding addresses stakeholder involvement in NRC's decision-making process on alternatives. The NA report considers broad participation as critical and, during the decision-making process, NRC should focus on the process itself, rather than prescribing an outcome for disposition of solid material, since the outcome must evolve from the process.

In general, NRC staff agreed with these findings. Regarding the first finding, previously published NRC documents state that potential exposures received as a result of released solid material are a fraction of public health guidelines, and that the current approach is flexible, useful, and well-understood by licensees; however, there are drawbacks with its use that could be eliminated by an alternative approach. The second finding is also consistent with previously published NRC documents, regarding use of an open process, for developing a National standard, consistent with the requirements of the Administrative Procedures Act (APA) and the National Environmental Policy Act (NEPA). In addition, this finding

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agrees with information NRC staff developed concerning use of an open process for evaluating health and environmental impacts and cost-benefit analyses, while taking into account stakeholder comments (5).

Recommendations of the NA Report and NRC Staff Review

The first recommendation is for NRC to devise a new decision framework to develop and evaluate a broader range of alternative approaches to the disposition of solid materials, including the current case-by-case approach, clearance, conditional clearance, and no release. This recommendation is consistent with information, previously published by NRC, regarding using an APA and NEPA process to evaluate the full range of alternatives for the control of solid material, as well as factors such as health and safety, environmental impacts, cost-benefit, implementation, international and National standards, and affected stakeholders. The NRC staff had previously noted the need for additional analyses, and evaluation of other factors, to support decision-making for all the alternatives in SECY-00-0070. Thus, NRC staff agrees with the recommendation to study all alternatives and associated impacts and other factors listed in the NA report, which is consistent with on-going NRC studies in this area.

The second recommendation is that NRC's decision-making process should be integrated with a broad-based stakeholder participatory decision-making process. The NA report suggested that this include: (1) NRC commitment to establish and maintain a meaningful and open dialogue with a wide range of stakeholders; (2) an ad-hoc advisory board that would advise NRC in its consideration of approaches for disposition of solid materials; and (3) assistance to NRC from outside experts to help: (a) establish an advisory board; (b) facilitate dialogue among NRC and stakeholders during the decision-making process; (c) assess portions of the stakeholder involvement program; and (d) make recommendations. The NRC staff agreed on the importance of a commitment to integrate stakeholder input into its decision-making process and noted that Agency policy and recent efforts on this issue have demonstrated a commitment to integrate broad-based stakeholder participation into the NRC decision-making processes. It is also recognized that, although the process could be difficult, it should address concerns about adequate stakeholder involvement, during the evaluation of alternatives for the control of solid materials.

The third recommendation is that NRC should adopt an overarching policy statement describing the principles governing the management and disposition of solid materials. The NA report considered a good starting point for developing such a policy would be review and discussion of International Atomic Energy Agency (IAEA) Safety Series No. 89 (SS89), with a broad-based stakeholder group, to provide a foundation for evaluating alternatives for control of solid material. The NRC staff agreed that it is important to have an overarching decision framework to govern the evaluation of this issue. The existing decision framework in the Strategic Plan in NUREG-1614 is similar to SS89, and is applicable to NRC's daily work. Therefore, the NRC staff considered it more efficient to use the Strategic Plan as a policy-level, decision framework that can be applied to the process that would be used for the control of solid material.

The fourth recommendation was that a dose-based standard should be employed as the primary standard when considering clearance or restricted use. The NA report also recommended that to implement such a standard, a range of scenarios must be considered, a critical group selected, and concentration levels, associated with the dose standard, developed that can be used in practice. The NRC staff agreed with the need to consider use of a risk-informed dose standard in this area.

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The fifth recommendation is that an individual dose standard of 10 microsieverts/yr (1 millirem/yr) provides a reasonable starting point for the process of considering options for a dose-based standard. This recommendation included five reasons why this particular value is considered reasonable, but did not provide a scientific discussion that advanced the understanding of risk management issues or resolve disagreements amongst stakeholders in this area. The NRC staff agreed that the stated dose level could represent a “starting” point in assessing alternatives, but noted that any process must consider other dose levels as part of the assessment of alternatives.

The sixth recommendation was that for any dose-based standard, NRC should use the conceptual framework of NUREG-1640 to assess dose implications. This recommendation included suggestions for completing technical work related to NUREG-1640. The NRC staff review of this recommendation noted that the NA report appears to indicate that all NRC technical work on the control of solid material is being conducted as part of NUREG-1640, which is erroneous. As discussed later in this paper, there are currently other technical analyses NRC is conducting in this area, and NUREG-1640 is purposely limited in scope to address only one part of the technical basis. In general, the NRC staff agreed that its assessment should include evaluation of all alternatives, including associated impacts and costs, and noted that such analyses were underway or NRC was considering them.

The seventh recommendation was that NRC should continue to review and assess the ongoing international effort on control of solid materials and develop a scientific rationale for consistency between concentration levels associated with dose criteria the United States and other countries may adopt. This recommendation is consistent with the NRC staff view that it is appropriate to compare NUREG-1640 with other international studies and to help develop IAEA standards, so that NRC can be knowledgeable about international approaches.

In summary, the NA report presents a process for moving forward on the control of solid materials issue, rather than a set of separate recommendations on how to control solid materials. Although the NA report discusses four basic technical approaches for control of solid material, it does not recommend one, and suggests that they be developed and evaluated as part of the process suggested in the NA report.

NRC'S DECISION TO CONDUCT A RULEMAKING ON CONTROL OF SOLID MATERIALS

In July 2002, the NRC staff presented to the Commission, in SECY-02-0133, a set of options for proceeding with a regulatory process for examining alternatives for control of solid material, based on the NA report and on other factors (13). The first option was to take no action and continue with the current approach for controlling solid materials. The rationale for this option was that the current approach is sufficiently protective of public health and does not need immediate revamping, although it has certain shortcomings. Under this option, the NRC staff would maintain the status quo and not conduct a rulemaking or other broad process, but could modify the current approach, by providing additional guidance on it, to improve consistency in implementation. A second option was to defer a process for moving forward and, instead, engage stakeholders on the NA report and review related activities. Under this option, the staff would defer rulemaking and would seek broad stakeholder input in review of the NA report. It would allow time for additional staff review of other related actions and some modification of the current approach for controlling solid materials as an interim measure.

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A third option was to conduct a process involving either a traditional rulemaking that did not have extensive public involvement, or a rulemaking that was enhanced in its public involvement. Also, the scope of a rulemaking could be narrow or broad, under either rulemaking approach.

The acceptability of establishing a National standard for the control of solid material depends on many interrelated factors. Public health and safety would be maintained under the options developed by the NRC staff, so an important consideration is how to best use Agency resources to achieve the goals of increasing public confidence, increasing efficiency and effectiveness, and reducing unnecessary regulatory burden on stakeholders. The staff recommended proceeding with a rulemaking process under the third option, because: (a) it seemed the best way to support licensing casework involving control of solid material; (b) it provided the opportunity for stakeholder involvement in the process; and (c) it is consistent with the APA and NEPA.

In October 2002, the Commission directed the NRC staff to proceed with an enhanced participatory rulemaking to develop specific requirements for the control of solid material at licensed facilities (14). The Commission stated that the rulemaking should give fair consideration to all alternatives in developing a proposed rule, as to identify a broad range of alternatives that the Commission can weigh in the future. As part of this effort, the staff was directed to seek stakeholder participation and involvement in considering alternative approaches, including the current case-by-case approach, clearance, conditional clearance, and a policy of no release.

The Commission also noted that considerable information-collection efforts have already been made on this issue, and that the staff should not duplicate these efforts, but use this information to focus on potential solutions. The Commission specifically directed the staff to explore and document the feasibility of conditional clearance. In discussions with stakeholders on this issue, the staff plans to obtain additional information to determine the feasibility of options for conditional clearance that are effective, reasonably possible to implement, and would increase public confidence in the process. The Commission requests to complete the overall rulemaking effort within 3 years of its October 2002 direction.

STATUS OF NRC STAFF ACTIVITIES

Based on the October 2002 Commission direction, the staff is proceeding with rulemaking efforts. The first step in this process is preparation of a rulemaking plan for developing a proposed and final rule, along with the accompanying regulatory analyses, implementing guidance, and venues for obtaining additional stakeholder input. A second step is issuance of a Federal Register notice to reopen the 10 CFR Part 51 environmental scoping process initiated in 1999, by soliciting additional stakeholder input on related environmental issues, in accordance with NEPA. The notice also invites stakeholders to a workshop to obtain additional information on alternatives for control of solid material, specifically with regard to the viability and feasibility of conditional clearance. Other components of the rulemaking plan include continuation of the NRC staff's activities related to National and international initiatives in this area, and continuation of the technical basis development, summarized below. As part of the overall plan to solicit stakeholder input on this topic, the NRC staff plans to use web-based methods, via the NRC website location regarding control of solid materials (15).

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Individual Dose Assessments

A draft report, "Radiological Assessments for Clearance of Equipment and Materials from Nuclear Facilities," NUREG-1640 (16), provides a method for estimating the hypothetical dose an individual might receive from residual radioactivity in solid materials. The materials analyzed in the report are iron, steel, copper, aluminum, concrete, and equipment released to general U.S. commerce from a nuclear facility.

In addition to the public comments received on this draft report, the Center for Nuclear Waste Regulatory Analyses (CNWRA) independently reviewed the reports technical contents and concluded that the draft analyses were high-quality. As part of its contract to consider possible alternatives for control of solid material, the NA reviewed draft NUREG-1640, along with other technical documents. The NA report stated that it provides a "conceptual framework" which best represents the current state of the art in risk assessment. The NA committee also reviewed and confirmed the reasonableness of several dose factor analyses. However, the NA report also provided a recommendation for additional technical work on NUREG-1640, some of which was being done as part of separate tasks under the overall technical basis development, as described below. Publication of a final version of NUREG-1640 is planned for 2003.

Assessment of Individual Doses for Soils

The NRC staff is developing a technical basis for estimating potential exposures if soil is released from NRC-licensed facilities. Similar to the development of draft NUREG-1640, the first part of this effort included developing information on the ways in which soils are transported and/or reused in commerce or by the general public in the United States. The NRC staff conducted an information search, in cooperation with the U.S. Department of Agriculture's National Agricultural Library, and, in January 2002, published report NUREG-1725, "Human Interaction with Reused Soil: A Literature Search" (17). This information can be used in characterizing scenarios, estimating parameters, and selecting models for soil reuse for dose assessment.

The second part of this effort was to conduct an analysis of scenarios, parameters, and resultant dose factors. NRC began a preliminary dose assessment intended to provide an analysis, based on reasonable scenarios and parameters. Four scenarios were included in the preliminary assessment: (1) farm/field worker; (2) truck operator; (3) recreational user; and (4) rural resident baseline scenario for comparison with technical support analysis for the 1997 rulemaking on license termination. The dose modeling was coordinated with similar efforts for sewage sludge, being conducted by the Interagency Steering Committee on Radiation Standards (ISCORS), and for metals and concrete in Draft NUREG-1640, to use established technical bases and common scenarios. A preliminary dose assessment was completed in January 2002 and a more detailed dose assessment is currently underway, which includes additional technical development of exposure scenarios and further coordination with the ISCORS subcommittee on sewage sludge.

Other Solid Materials

Individual dose factors are being developed for materials that could be available for release as part of routine operations at the variety of facilities NRC licenses, including: hospitals; clinics; research, medical,

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and industrial laboratories; power plants; research reactors; and fuel facilities. Such materials include rubbles and sediments, lead, glass, paper, wood, plastic, and ordinary trash (a composite category of routine disposals for landfill). The dose conversion factors for these other materials are planned for inclusion as a supplement to NUREG-1640.

Comprehensive Analyses of Alternatives

Factors that will be considered in evaluating potential alternatives for control of solid material include human health and environmental impacts, cost-benefit considerations, impacts on other industries, resource conservation, the capability to survey material, and stakeholder input. NRC would consider a broad range of potential radiological and non-radiological impacts in its evaluation, including evaluation of doses to individuals, assessment of collective doses to different population groups, impacts on biota, and societal impacts, etc. Executive Order 12291 requires Federal agencies, as part their decision-making, to consider cost-benefit evaluations of alternative courses of action, including costs to licensees, the public, and other affected industries. The NRC staff is currently obtaining related information on costs; inventories of material potentially available for release; doses to individuals and doses to collective populations, if that material were released; and doses to an individual, based on exposure to multiple items. This information, along with implementation considerations, will be incorporated into a Draft Generic Environmental Impact Statement that is planned for publication for public comment.

Radiological Survey Methods

The NRC staff is also developing information on methods that could be used for performing radiation surveys to control solid material, for the alternatives under consideration. Draft Report NUREG-1761, entitled "Radiological Surveys for Controlling Release of Solid Materials," was published for public comment in July 2002 (18). NRC received a number of technical comments on this report from industry, State regulatory groups, and other stakeholders. The technical approaches contained in NUREG-1761 will be considered in developing a supplement to the Multi-Agency Radiation Survey and Site Survey Manual (MARSSIM) [published by NRC as NUREG-1575 (19)], that will address control of solid materials. Also, the staff is continuing work on the application of the Spatial Analysis and Decision Assistance (SADA) executable program, which the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) developed to implement MARSSIM concepts. SADA provides a number of integrated tools in geospatial modeling, spatial analysis, visualization, statistical analysis, and sampling design.

Other Factors Affecting Decision-Making

NRC staff has continued to stay informed of international initiatives in this area, potential import and trade issues, and domestic activities, since harmonization among Federal and international regulatory agencies would simplify the management of these materials. International and domestic initiatives include technical and policy issues that play an important role in the decision-making process on the control of solid material. Two major international radiation protection organizations -- the Commission of European Communities and the IAEA -- are attempting to harmonize international clearance standards and implementing guidance. In the past 2 years, the IAEA has included in its clearance efforts the development of a Draft Safety Guide and associated supporting technical documents on specification of

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radionuclide content in commodities requiring regulation for purposes of radiological protection. Draft Safety Guide DS-161, "Specification of Radionuclide Content in Commodities Requiring Regulation for Purposes of Radiological Protection," is being developed with the help of several consulting international organizations. The staff has participated actively in these consultant meetings.

In the United States, EPA has responsibility for setting generally applicable environmental standards under the Atomic Energy Act, but is not pursuing a rulemaking in this area at this time. Although EPA has suspended development of a domestic standard for clearance, it has continued to develop dose factors for translating radioactivity in cleared metal to the dose a person would receive. This is a continuation of the collaborative work between NRC and EPA staffs in developing technical information bases on scenarios and pathways related to potential exposures. EPA presented technical information to the NA, including a summary of EPA's ongoing technical basis work on scenarios, pathways, and parameters and comparisons of domestic and international clearance studies. Recently, EPA added analyses of copper and aluminum to the existing analysis of carbon steel, which is contained in a revised Technical Support Document that is posted on EPA's Clean Materials Program website (20). EPA is currently focusing on orphan source issues and on the interception of imports with sufficient radioactive content to warrant regulatory control.

The staff has also worked with the DOE to better understand and collect information and data on various aspects of DOE's current and future metals recycling program, to assess how NRC staff might consider various DOE scenarios when estimating potential doses. NRC staff plans to evaluate information contained in DOE's draft Programmatic Environmental Impact Statement.

Coordination amongst Federal agencies on this topic is active through the Recycle subcommittee of ISCORS. At the State level, NRC staff and Agreement States continue to receive requests from licensees to recycle, reuse, or dispose of solid material, which are reviewed on a case-by-case basis, using current practices and guidelines. The NRC staff issued three memoranda clarifying the use of these current practices and guidelines, for licensing decisions involving the control of solid materials, on August 7, 2000; July 27, 2001; and December 27, 2002. These memoranda were provided to the Agreement States as information in All Agreement States Letter No. STP-00-0070, dated August 22, 2000; No. STP-01-081, dated November 28, 2001; and No. STP-03-003, dated January 15, 2003 (21, 22, 23).

As part of the rulemaking effort, NRC staff intends to evaluate the applicability of a standard issued by the American National Standards Institute, Inc., (ANSI)/Health Physics Society (HPS) N13.12-1999 (24). According to the National Technology Transfer and Advancement Act of 1995, Federal agencies are to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless the use of such standards is inconsistent with applicable law or otherwise impractical. ANSI/HPS N13.12-1999 contains guidance on the clearance of solid materials, based on an individual dose limit of 10 microsieverts/yr (1 millirem/yr) or higher dose levels, when justified on a case-by-case basis. The NA did not evaluate this ANSI standard, but noted that it contained useful information and addressed implementation protocols. Previously, NRC deferred judgment on the adoption of this ANSI/HPS standard, but now plans to take the information in the ANSI/HPS standard into consideration on the path forward for the control of solid materials.

Another consideration is a report that was published by the National Council on Radiation Protection and Measurements (NCRP) in November 2002, entitled "Management of Potentially Radioactive Scrap

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Metal” (25). This report contains 13 findings and recommendations that summarize the NCRP's position on disposition of potentially radioactive scrap metal from facilities regulated by NRC, DOE, and States. It advocates waste minimization, identifies alternatives to the existing approach for managing potentially radioactive scrap metal, and offers a radiation protection framework for clearance. It also acknowledges the role of public acceptance in establishing a regulatory procedure and advocates the development of National and international dose- or risk-based standards. The conclusions of the report may be applicable to managing the disposition of other solid materials also.

CONCLUSION

Based on a variety of factors, NRC has decided to conduct an enhanced participatory rulemaking to develop specific requirements for the control of solid material at licensed facilities. As part of this effort, NRC staff will give fair consideration to all alternatives in developing a proposed rule, so that a broad range of alternatives is identified for Commission consideration. The NRC staff will continue its technical basis development, remain knowledgeable about National and international activities, and engage stakeholders through participation and involvement in the alternatives under consideration, which principally are the current case-by-case approach, clearance, conditional clearance, and a policy of no release. As directed by the Commission, the NRC staff will obtain additional information to determine the feasibility of options for conditional clearance that are effective, reasonably possible to implement, and capable of increasing public confidence in the process. The current schedule is to issue a final rule and supporting information in 2005.

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