

## **RULEMAKING ISSUE NOTATION VOTE**

March 31, 2005

SECY-05-0054

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

SUBJECT: PROPOSED RULE: RADIOLOGICAL CRITERIA FOR  
CONTROLLING THE DISPOSITION OF SOLID MATERIALS  
(RIN 3150-AH18)

### PURPOSE:

To request Commission approval for publication of a proposed rule in the *Federal Register* to amend 10 CFR Part 20, "Standards for Protection Against Radiation," to include radiological criteria for controlling the disposition of solid materials that have no, or very small amounts of, residual radioactivity resulting from licensed operations, and which originate in restricted or impacted areas of Nuclear Regulatory Commission (NRC)-licensed facilities.

### SUMMARY:

In response to the Commission's October 25, 2002, Staff Requirements Memorandum (Attachment 1), the staff has conducted an enhanced participatory rulemaking on controlling the disposition of solid materials and is requesting Commission approval of publication of a proposed rule. This paper provides the Commission with the draft *Federal Register* notice (FRN) (Attachment 2) containing the "Statement of Considerations" for the rulemaking and the proposed rule text. This paper also provides the Commission with the draft Generic Environmental Impact Statement (DGEIS) (NUREG-1812) (Attachment 3) and the draft regulatory impact analysis (Attachment 4).

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## BACKGROUND:

NRC's existing regulations contain a framework of radiation standards to ensure protection of public health and safety from the routine use of materials at licensed facilities. These standards include a public dose limit in 10 CFR Part 20 and dose criteria for certain types of media released from licensed facilities, such as airborne and liquid effluents. However, Part 20 does not contain a specific dose criterion to be used to verify that solid materials being considered for release have no, or very small amounts of, residual radioactivity. Instead, NRC's current approach is to make decisions on disposition of solid materials by using a set of existing guidelines, primarily based on survey instrument capabilities. In a report reviewing NRC's current approach, the National Academies indicates that the current approach is "sufficiently protective of public health and safety that it does not need immediate revamping." However, because the current approach does not derive from a specific regulation, NRC's decisions in this area are inefficient in that they lack an overall risk basis, consistency, and regulatory finality. Therefore, the proposed rule is intended to improve NRC's regulatory process by incorporating risk-informed criteria into the Commission's regulations for disposition of solid material.

The staff has engaged in several information gathering-activities as part of its decision-making for this rulemaking and has actively sought stakeholder participation and input on alternate disposition approaches. Activities to solicit stakeholder input have included requesting public comment in the *Federal Register* in June 1999 and February 2003 on issues associated with rulemaking in this area. In response, the staff has received nearly 3500 letters and e-mails, from a range of different stakeholder groups, that present a diverse set of views. The staff held nine public meetings to solicit stakeholder views between September 1999 and February 2005. In addition, at the Commission's request, the staff supported a study by the National Academies to obtain an independent review of the issues and alternatives. In preparing its report, provided to the Commission in March 2002, the National Academies held three meetings with stakeholders between January and June 2001.

As part of its information gathering, the staff reviewed various related reports prepared by recognized national and international organizations such as the National Academies; the National Council on Radiation Protection and Measurements (NCRP); the American National Standards Institute (ANSI); and the International Atomic Energy Agency (IAEA). These organizations have issued findings about possible criteria for controlling the disposition of solid materials. In addition, the staff considered reports suggested by stakeholders. The staff also considered other relevant Federal and international standards in this area. Finally, as part of its information gathering, NRC completed several technical studies to evaluate alternatives for controlling the disposition of solid materials. The results of these studies have been incorporated into the DGEIS.

As part of this rulemaking effort, the staff is maintaining a website on NRC's activities regarding the disposition of solid materials at [www.nrc.gov/materials.html](http://www.nrc.gov/materials.html). The website has information

about current activities, relevant documents, opportunities for public comment, and summaries of public comments received to date.

#### DISCUSSION:

As noted, the principal reason for this rulemaking is to improve the efficiency and effectiveness of the NRC regulatory process by establishing criteria for the disposition of solid materials in the regulations. In conducting this rulemaking, the staff has been guided by the goals in the NRC Strategic Plan of which the primary goal is ensuring the protection of public health and safety and the environment. In addition, as described in the Strategic Plan, the staff is conducting the rulemaking process in an open manner so that stakeholders are informed and involved in the process as appropriate.

The staff is proposing to amend NRC's regulations to establish requirements having the following elements:

- (1) Limited allowed disposition paths: Solid material, meeting the dose criterion of #2, below, may be released from licensed control if sent to: (a) disposal in Environmental Protection Agency (EPA)/State-regulated landfills; (b) re-use in a pre-defined set of uses (specifically concrete in road bed construction and re-use of tools and equipment); or (c) other disposition paths, if supported by a case-specific analysis and approval of proposed procedures.
- (2) A dose criterion set at 1 millirem per year (mrem/yr) [0.01 milliSievert per year (mSv/yr)]: This dose criterion is based on scientific analysis and regulatory considerations and is a generic constraint set well below levels established to ensure adequate protection of public health and safety.
- (3) Tables of volumetric and surface nuclide concentration levels associated with the dose criterion of 1 mrem/yr [0.01 mSv/yr]: Solid material would be considered acceptable for release if its nuclide concentrations did not exceed the levels in the tables.
- (4) A recordkeeping system: Maintenance of records provides reasonable assurance that disposition of the solid material has been conducted in accordance with the provisions of the proposed amendment.

The staff discussed with stakeholders and gathered information about a range of alternate approaches for disposition of solid material. These alternates included a rule allowing unrestricted release of solid material (i.e., the clearance approach); an approach in which all solid material goes to a licensed low-level waste (LLW) disposal facility (i.e., the prohibition approach); and a limited disposition approach.

The staff has decided to propose a limited disposition approach that it believes is a balanced consideration of technical issues and overall stakeholder concerns. The proposed approach would limit release of solid material, meeting a 1 mrem/yr [0.01 mSv/yr] dose criterion, from licensed control to the set of limited disposition paths, noted above. This approach is consistent with NCRP Report No. 141, which suggests an approach that would initially prohibit recycling into certain consumer products and which notes that it is possible to designate certain acceptable restricted industrial uses where direct contact of solid material with the general public can be minimized and avoided. Similarly, the National Academies' report also notes the

merits of an approach focusing on restricted uses and/or landfill disposal. This approach is also consistent with the diverse range of stakeholder comments that sought uniform standards for release, but which were either concerned about unrestricted releases or did not specifically support an unrestricted release approach.

Some stakeholders saw the limited disposition path approach as a means to provide additional protection of public health and safety, whereas others expressed concern about the feasibility and potential regulatory burden of limited disposition paths and about their ability to limit where material goes and protect public health and safety. As discussed in detail in Sections III.B.1.1 and III.B.1.2 of the attached FRN, the staff believes that the provisions in the proposed amendment provide reasonable assurance that doses will be maintained well below levels established to protect public health and safety and that unnecessary burden will be minimized. These provisions include: direct material to allowed destinations, including facilities under the regulatory structure of the Resource Conservation and Recovery Act (RCRA); establish a dose criterion that is a small fraction of the public dose limit in 10 CFR Part 20; place bounds on nuclide concentrations; and require maintenance of records. The staff does indicate in the FRN that it is interested in stakeholder input as to practices at various types of EPA/State-regulated RCRA landfills and specifically requests comment regarding this matter in the FRN.

Although the proposed rule would authorize disposal of solid material from NRC-licensed facilities to an EPA/State-regulated RCRA landfill facility or to a specific end user, it is the operator (or regulator) of each landfill facility and/or other recipient who will determine if a transfer to a specific facility will be allowed. Licensees will have to be aware of monitoring practices for incoming shipments to landfills or other destinations as part of their business practices, in addition to complying with the requirements of this proposed amendment for releasing solid material from further licensed control.

If a licensee chooses not to use one of the disposition paths allowed in the proposed amendment, it may request case-specific approval of another disposition path. Disposition paths considered as part of a case-specific request would include, in particular, metal recycle and soil disposition. Developing scenarios for use in the DGEIS for disposition of metals and soil is difficult, and neither stakeholders nor our technical analyses have provided a clear process as to how these materials could be generically directed for recycle or re-use into non-licensed industrial or construction related end uses. Thus, the proposed amendment indicates that any consideration of disposition of metal or soil should be proposed by a licensee as a case-specific request.

A 1 mrem/yr [0.01 mSv/yr] dose criterion is a small fraction (1/100) of NRC's public dose limit in 10 CFR Part 20 established to provide adequate protection of public health and safety. It is also in the range of Federal agency standards and allowable risk ranges for other similar media, like air and liquid effluent requirements in 10 CFR Part 50, Appendix I, and EPA drinking water standards in 40 CFR Part 141. A 1 mrem/yr [0.01 mSv/yr] dose criterion also comports with technical findings in reports prepared by various recognized scientific organizations. In particular, NCRP Report No. 141 notes that a dose below 1 mrem/yr [0.01 mSv/yr] can be defined as a "negligible individual dose," and that doses that fall into this range have an associated average annual excess risk below which "...efforts to reduce radiation exposure to the individual is unwarranted." NCRP Report No. 141 also cites several health effects studies and notes that this dose is in a risk range ( $10^{-7}$  to  $10^{-6}$  per year) that is generally regarded as "trivial." A dose criterion of 1 mrem/yr [0.01 mSv/yr] represents a minute fraction (1/300) of

natural background and also is a small fraction of the variability in natural background across the U.S. that members of the public are exposed to without health impact. The staff is cognizant of reports on low doses of radiation cited by citizen groups that are different from the current scientific consensus views. However, the staff is confident in the information it does have to determine that a proposed standard of 1 mrem/yr [0.01 mSv/yr] is an appropriate dose criterion for this proposed rule. More detail on the 1 mrem/yr [0.01 mSv/yr] dose criterion is provided in the attached FRN, Section III.B.2, including a discussion of consistency with other NRC and EPA standards, relationship of the dose criterion to recommendations from national and international scientific bodies, comparability to background radiation, and effect of exposures from multiple sources.

The staff plans to supplement the proposed rule's dose criterion of 1 mrem/yr [0.01 mSv/yr] with tables of measurable nuclide concentration levels to facilitate confirmation that the dose criterion has been met. Several organizations have developed reports (including the NRC in NUREG-1640; IAEA in RS-G-1.7; and ANSI in N13.12-1999) that relate measurable nuclide concentrations to a dose of 1 mrem/yr [0.01 mSv/yr]. Each of these reports evaluates various exposure scenarios and pathways by which potential population groups might be exposed, based on release of a range of materials and nuclide concentrations. The appropriateness of the models in NUREG-1640 to evaluate the relationship between material released and a dose criterion of 1 mrem/yr [0.01 mSv/yr] was reviewed by the National Academies and peer-reviewed as part of the report's preparation. The National Academies report noted the technical soundness of NUREG-1640 and recommended that for any dose-based approach for disposition of solid materials, the NRC should use the conceptual framework of NUREG-1640 to assess dose implications. Table 2 of IAEA's RS-G-1.7 contains volumetric concentrations for nuclides of artificial origin, developed independently from NUREG-1640. The staff has reviewed Table 2 and found its concentrations reasonably consistent with NUREG-1640. An advantage of using the internationally accepted nuclide concentrations in RS-G-1.7 in this proposed NRC amendment is that it would promote consistency among nations in setting numeric standards for release of solid material from regulatory control.

Thus, the staff has decided to use Table 2 of RS-G-1.7 in this proposed amendment because it would make NRC's release concentrations consistent with international numeric standards. In addition, our review of RS-G-1.7 and NUREG-1640 indicates that the use of either document can provide reasonable assurance that the dose criterion in this proposed amendment is met. More detail on the bases for the nuclide concentrations is provided in the attached FRN, Section III.B.3.

The staff had to make decisions on two specific issues with regard to nuclide concentration tables. First, for nuclides not included in Table 2 of RS-G-1.7, the staff is using nuclide levels taken from NUREG-1640 normalized to the 1 mrem/yr [0.01 mSv/yr] dose criterion of this proposed amendment. Primarily, this includes licensees authorized to possess source material under 10 CFR Part 40 and special nuclear material under 10 CFR Parts 50, 70, and 72. Second, RS-G-1.7 does not yet contain limiting values for surface nuclide concentrations. Therefore, the staff has developed a table of acceptable surface concentration levels. In developing this table, the staff noted that solid materials released from further license control by the NRC under this proposed amendment would likely be transported in a variety of manners and that consistency between NRC requirements and Department of Transportation (DOT) regulations in 49 CFR Part 173 for transport of material is important. The staff decided to use surface concentrations based on the definition in 49 CFR 173.403 for surface concentrations

not requiring DOT regulation to provide consistency between these two Federal agencies regarding material needing no further regulation. Although the DOT values are not a direct derivation from a 1 mrem/yr [0.01 mSv/yr] dose level, they result in doses of less than 1 mrem/yr [0.01 mSv/yr] and are also reasonably consistent with existing values in Regulatory Guide 1.86. In considering how to proceed in this area, the staff also derived estimates of surface concentrations directly from the volume concentrations in RS-G-1.7 using information in the DGEIS for ratios of the mass of various solid materials to their surface areas. The DOT values are reasonably consistent with these derived surface concentrations for certain nuclides (such as Co-60 and Cs-137) and for typical mixes of nuclides, although for some nuclides the DOT values may introduce additional conservatism resulting in more restrictive concentration levels. The staff is particularly interested in stakeholder views on the approach it has taken, and in the FRN specifically requests input from stakeholders on this item.

The volumetric and surface nuclide concentration tables are contained in a new Appendix E to 10 CFR Part 20. These tables provide an acceptable means to comply with the 1 mrem/yr [0.01 mSv/yr] dose criterion in an effective and efficient manner. Licensees may elect to calculate case-specific nuclide concentrations under the case-specific element of this proposed amendment.

The proposed amendment would require licensees to maintain records of material released (e.g., type and quantity of solid material, and nuclides present and their concentrations) and, as appropriate, its destination (e.g., the landfill or specific end use shipped to, etc.). The records required by this proposed amendment will provide for verification during routine inspections that the dose criterion has been met and provide reasonable assurance that the material was dispositioned in accordance with this proposed amendment. More detail on recordkeeping requirements is provided in the attached FRN, Section III.B.4.

Section III.C of the FRN discusses the scope of this proposed amendment and interfaces with other NRC requirements. One of the specific areas noted is that all materials in restricted or impacted areas would be subject to the provisions of the proposed amendment. However, it is also noted that making decisions on disposition of solid material based on its location in a "restricted area" may not be appropriate because the definition of restricted area in 10 CFR Part 20 may relate more to exposure to ambient external radiation fields than to residual radioactivity on solid material. Thus, it is noted that a more appropriate scope may be only material in "impacted areas" which is currently defined in 10 CFR Part 50 as "areas with some reasonable potential for residual radioactivity in excess of natural background." In the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (NUREG-1575) this term, "impacted area" is used to signify the extent of surveys needed to release areas from licensed control. It would seem reasonable that this proposed amendment should have a similar requirement to allow for better focus by the NRC and licensees on disposition of solid materials from those areas where a reasonable potential for the presence of residual radioactivity exists. In the FRN, the staff specifically requests input from stakeholders on this item.

An interface with other NRC requirements is the relation to 10 CFR 20.2002. Currently, under the provisions of 10 CFR 20.2002, licensees can apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations, to dispose of licensed material. The proposed amendment would not change that provision. A licensee can continue to use the existing provisions of 10 CFR 20.2002 to request disposal of materials not within the scope of this proposed amendment and also to request consideration of alternate dose levels

for materials covered by this proposed amendment (for example, if a specific landfill is permitted by EPA or State regulator to receive material with a potential dose greater than that in this proposed amendment).

### Discussion of the Rulemaking Process

The staff has participated in 12 meetings (from September 1999 to February 2005) with a range of stakeholder groups, and received over 3500 separate comment letters and e-mails (in response to June 1999 and February 2003 FRNs) representing viewpoints from a wide range of stakeholders. Information gathered in this effort has included: identification of economic concerns by the metals and cement industries; citizens groups concerns over the potential presence of radioactivity in solid materials, even in very small amounts, in consumer products and general commerce; reference to various studies regarding low doses of radioactivity; identification of practical issues of how solid materials are handled at the range of facilities that NRC licenses; issues of feasibility related to limiting solid materials to only a set of defined uses; and various viewpoints associated with disposal of solid materials in RCRA landfills. The staff believes that this proposed rule represents a reasonable position based on the information-gathering process it has conducted. The evolution of alternatives, from the range of alternatives initially discussed with stakeholders to the present content of the proposed rule (i.e., the limited disposition approach), clearly indicates that the NRC carefully considered stakeholder views, as well as various technical reports and related health standards and development of technical bases and the DGEIS analyses on disposition of solid materials, in formulating this proposed rule. The staff is issuing this proposed rule and DGEIS for public comment and also is considering discussing this issue further with stakeholders in two public meetings to solicit additional input on these documents.

### Comments from Cooperating Agencies

The EPA, the Department of Energy (DOE), and the State of Massachusetts, identified as a State representative by the Conference of Radiation Control Program Directors and the Organization of Agreement States, have participated as cooperating agencies in the development of the DGEIS and submitted written comments on the DGEIS. The Naval Nuclear Propulsion Program (NNPP), a joint DOE/Navy program, also participated in the cooperating agency reviews at the request of DOE. In their comments on the DGEIS (Attachment 5), the agencies indicated that, in general, they found little difference in the environmental impacts between the current approach, the unrestricted release alternate, and limited disposition alternate; thus, they concluded the DGEIS analysis does not provide a compelling basis for selecting the limited disposition alternative. The NNPP indicated that it disagrees with the proposed limited disposition alternative, preferring instead the unrestricted release alternate. The cooperating agencies also recommend there should be an unrestricted release process for clearing material with no residual radioactivity from a restricted area. In addition, the agencies commented that there could be confusion regarding imports from other countries to the U.S. if those countries follow the IAEA safety guide which recommends unrestricted release for solid material meeting a 1 mrem/yr [0.01 mSv/yr] dose criterion, whereas the DGEIS recommends limited disposition. The cooperating agencies also made specific comments on the technical analyses in the DGEIS.

AGREEMENT STATE ISSUES:

A copy of the draft FRN for the proposed rule was posted on NRC's Technical Conference Forum for review by Agreement States. Input was received from the States of Massachusetts, Texas, and Washington (Attachment 5). In general, it was stated that there may not be a technical reason for this rule (with reference to the National Academies finding that the current approach is "sufficiently protective"), that there should be provisions for unrestricted use, and that the dose criterion is well below that needed to protect public health and safety and below constraints for other media such as liquid and gaseous effluents. Input was also received indicating the need for a provision for unrestricted release of material that was clean and/or had non-detectable activity. There also were questions regarding oversight of this material once it is released from the NRC license and how handling, inspections, or enforcement in the public domain would take place to ensure that the material stayed at the destinations allowed in the proposed amendment. There was also concern that the landfills may not take material released and that the case-specific approach may not be feasible for the metals and for soils. There also was some question about interface between this proposed amendment and the provisions of 10 CFR Part 20, Subpart E, on license termination of sites and provisions for on-site dispositions of solid materials. The staff believes that these comments have been considered in preparation of the draft FRN.

Based on the Management Directive 5.9 process, the staff has assigned compatibility categories to the sections of the proposed rule. Some Part 20 sections remain the same, in particular the Category C designation of 10 CFR 20.2001 and the Category A designations in 10 CFR 20.1003. Proposed 10 CFR 20.2008 and 20.2009 and proposed Appendix E to 10 CFR Part 20 have been designated Category B because there could be transboundary impacts with respect to transporting or distributing material released in accordance with both proposed sections and the appendix. The recordkeeping requirements in 10 CFR 20.2108(a) are categorized as Category C to ensure that licensees in Agreement States keep a minimum set of records important to keeping track of where the material goes.

RECOMMENDATIONS:

That the Commission:

1. Approve, for publication in the *Federal Register*, the attached notice of proposed rulemaking (Attachment 2).
2. Note:
  - a. A DGEIS has been prepared for this rulemaking (Attachment 3).
  - b. A draft Regulatory Analysis has been prepared for this rulemaking (Attachment 4).
  - c. An initial regulatory analysis of the impact of this proposed rule on small entities has been prepared as part of the draft Regulatory Analysis. Based on that analysis, the staff believes that this proposed rule would not have a significant impact on small entities. However, because it would be useful to have additional information on small entities as part of its analysis, the staff has specifically requested public comment on the potential impact of the proposed rule on small entities.

- d. The appropriate Congressional committees will be informed.
- e. A press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the *Federal Register*.
- f. The proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). These requirements must be submitted to the Office of Management and Budget for review no later than the date the proposed rule is forwarded to the *Federal Register* for publication.

RESOURCES:

It is anticipated that 3.5 NRC FTE will be needed to complete this rulemaking action (2.5 FTE NMSS and 1.0 FTE all other). These resources are within the approved budget for FY 2005 and FY 2006.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. Resources needed to complete this rulemaking action are within existing budget allocation. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of Information Services has reviewed this Commission Paper for recordkeeping implications and has no objections.

A copy of the draft FRN for the proposed rule was posted on NRC's Technical Conference Forum so the Agreement States could review it.

**/RA/**

Luis A. Reyes  
Executive Director  
for Operations

Attachments:

1. SRM Dated October 25, 2002
2. *Federal Register* Notice
3. Draft Generic Environmental Impact Statement
4. Draft Regulatory Analysis
5. Letters from Cooperating Agencies and Agreement States

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