January 27, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: RULEMAKING PROCESS IN RESPONSE TO THE STAFF REQUIREMENTS MEMORANDUM FOR SECY 98-028, "REGULATORY OPTIONS FOR SETTING STANDARDS ON CLEARANCE OF MATERIALS AND EQUIPMENT HAVING RESIDUAL RADIOACTIVITY"

PURPOSE:

To inform the Commission of the staff's intended rulemaking process in response to the Commission's direction in the Staff Requirements Memorandum (SRM) dated June 30, 1998, for SECY-98-028, "Regulatory Options for Setting Standards on Clearance of Materials and Equipment Having Residual Radioactivity."

BACKGROUND:

In a paper dated February 19, 1998 (SECY-98-028), the staff requested Commission direction on regulatory options for setting standards on clearance of materials and equipment having residual radioactivity.

In an SRM dated June 30, 1998 (Attachment 1), the Commission approved Option 3 (i.e. proceed independently to promulgate a dose-based regulation for clearance) and indicated that the rulemaking effort should begin in FY 1999.

DISCUSSION:

In response to the SRM directing the staff to implement Option 3, this paper discusses the rulemaking process that the staff intends to use to develop regulations for the clearance of materials and equipment having residual radioactivity. The paper also discusses major items impacting the rulemaking process and its schedule, and the staff's current activities and plans related to each of these items.

To expedite the rulemaking process, the staff formed a working group (WG) which includes technical staff from NMSS, RES, OGC, OSP, and NRR, and an Agreement State (A/S) representative from Texas. In addition, a steering group (SG), made up of NRC management from NMSS, RES, OGC, OSP, and NRR, and an A/S management representative from Illinois, provides continuing and direct management consultation for the WG to expedite preparation of, and concurrence in, rulemaking packages.

WG/SG staffs have discussed the Commission's plans outlined in the SRM at two meetings of the Interagency Steering Committee on Radiation Safety (ISCORS) in September and December 1998, at the All-Agreement States meeting in October 1998, and at a Department of State (DOS) workshop in December 1998.

As directed in the SRM, the staff plans to supplement the standard rulemaking process by including an enhanced participatory process similar to that used in revisions to Part 35 that will include facilitated public meetings before drafting any proposed rulemaking language, to solicit early public input on the major issues of the rulemaking. To support the enhanced activities, the staff is preparing an issues paper, to be used as a starting point for discussions at the public meetings. These actions are discussed in more detail in the following sections of this paper.

After the period of early public input, the staff will proceed directly to preparation of a proposed rule rather than prepare a rulemaking plan. This procedure would depart somewhat from the process outlined in MD 6.3. The rationale for this approach includes: (1) the June 30, 1998, SRM provided clear direction to the staff regarding procedures for rulemaking and general rule content (i.e., proceed in a manner similar to Part 35, which did not use a rulemaking plan; prepare a dose-based standard focusing on codified clearance levels above background that are protective of public health and safety; etc.); (2) the WG/SG have A/S representation that will facilitate A/S comments at an early stage; (3) a draft of the issues paper and proposed rule will be placed on NRC's Technical Conference Forum website dedicated to A/S participation and comment on rulemakings and draft guidance of a predecisional nature; and (4) the enhanced process, including the issues paper, public meetings, and Commission briefing on the meeting results, provide input to the rule process similar to that of a rulemaking plan.

1. **Issues associated with the rulemaking process**

a) **Enhanced Participatory Process - Issues Paper and Facilitated Public Meetings**

In response to the SRM, and in a manner similar to the Part 35 process, the staff's plan for enhanced public input will include use of NRC's Rule Forum website. In addition, the staff will convene facilitated public meetings in four different geographical locations (Chicago, Atlanta, San Francisco, and Washington, DC). These public meetings will provide a forum by which NRC can obtain input and rationales from a variety of viewpoints on major issues related to rulemaking on clearance, although they will not attempt to reach a consensus on the issues. These facilitated public meetings will also satisfy the requirements of the scoping process for preparation of an environmental impact statement (EIS) as required by 10 CFR 51.26-29. Two key components of the enhanced process are preparation of an issues paper for use at the public meetings and the use of a facilitation process for the meetings.

1) Issues paper - An issues paper will be made publicly available, before the public meetings, to provide background for discussion of

major issues. A similar process was used successfully for the public meetings for the recently issued license termination rule. It is anticipated that the issues paper will discuss, in a broad way, whether NRC should proceed with rulemaking on clearance; and if a rulemaking does proceed: (a) what materials should be covered; (b) how should health risks, economic factors, and other existing international and national criteria be factored into decision-making; (c) should some form of restrictions on future use of material be considered; and (d) should criteria be stated in terms of risk, dose, or activity. The issues paper will provide the pros and cons of each option, as well as specific items for discussion under each issue.

The staff will provide an information copy of the issues paper to the Commission in March 1999, before announcing its availability in the Federal Register.

2) Facilitation of Public Meetings - Staff experiences with both the license termination rule and the Part 35 rulemaking indicate that public meetings are more productive if they are facilitated. A facilitator's role is to broaden participation in the meetings to include a range of groups and a variety of viewpoints, and to aid in conducting the meetings so that those viewpoints are heard. The role of facilitator could either be filled by persons external to NRC (and under contract to NRC) or internal to the Agency (NRC staff). The staff has determined that it would be most productive and cost-effective to use a combined external/internal team approach to facilitation. The staff is proceeding to place the contract for the external facilitation aspects.

b) **Development of Technical Basis Needed for Proposed Rule**

As discussed in SECY-98-028, technical basis development consists of several important components needed to support a proposed rule on clearance. These components (which include a National Environmental Policy Act (NEPA) analysis, a regulatory analysis (RA), and an implementing regulatory guide to be issued concurrently with the proposed rule), and the technical bases needed for each component, are described in Attachment 2 and noted as follows:

1. Preliminary technical basis report: To provide the needed baseline input to the NEPA analysis, RA, and regulatory guide, a draft NUREG/CR has been prepared which provides dose factors for individuals exposed to specific cleared items, through a wide variety of scenarios. The materials addressed in this technical basis include scrap steel, copper and aluminum, and concrete rubble, as well as tools for reuse. This report has been peer-reviewed by an NRC contractor, updated to consider probabilistic exposure scenarios, and compared with a technical basis document prepared by EPA. Currently, this report has been reviewed by NRC staff and will be published for public comment in January 1999 so that it is available as background for the public meetings.

2. NEPA analysis and RA: It is necessary to consider and weigh the environmental impacts of rulemaking alternatives in an EIS or environmental assessment (EA) to satisfy NEPA requirements. It is expected that, given the breadth of issues and impacts associated with clearance, an EIS will be prepared similar to that prepared for the license termination rule in NUREG-1496, "Generic Environmental Impact Statement in Support of Radiological Criteria for Decommissioning of NRC-Licensed Nuclear Facilities." NUREG-1496 evaluated both radiological and non-radiological impacts associated with alternative dose criteria for release of lands and structures for unrestricted and restricted use. It will also be necessary to assess the cost-benefits of rulemaking alternatives in a regulatory analysis.
3. Regulatory guidance: To support implementation of the rule, the staff will be preparing a regulatory guide on measurement methods for low concentrations of volumetrically contaminated material that may exist in various equipment and material types, shapes, and sizes that are anticipated to be available for clearance. It is expected that analyses similar to that prepared for the license termination rule in NUREG-1505, "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys," will be prepared to support a clearance regulatory guide.

The staff is currently preparing statements of work for the specific technical information identified in Column 3 of the table in Attachment 2. The additional technical basis development needed for this rulemaking will be conducted by RES, in accordance with Commission direction in response to SECY-97-220, "Implementation of DSI 22." NMSS will continue to lead the associated rulemaking efforts.

c) **Scope of Materials Covered by Rule**

The June 30, 1998, SRM stated that all metals, materials, and equipment, including soil, should be covered in the rule, although it indicated that a narrower scope could be justified based on problems with applying the rule to certain categories of materials. The staff's current plans for the scope of the rulemaking are as follows:

1. The current technical basis includes a set of materials and equipment that makes up the large majority of material that would likely be considered for clearance at licensed NRC facilities. These materials would be included in the rulemaking.

2. In addition, it is clear from staff experience and from information received from licensee groups that it is important that the rulemaking also covers clearance of soil. Although the technical report referred to above does not include soil, work done previously for the license termination rule in NUREG-1496; NUREG/CR-5512, "Residual Radioactive Contamination from Decommissioning;" and NUREG-1549, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination," provide baseline technical information on individual dose factors and cost-benefit analysis for soil that the staff plans to adapt for use as part of this rulemaking. Thus, it is planned that the scope of the current rule will include soil.
3. The current technical report does not include sludges, resins, glass, and wood products, etc. Although the staff proposes to expand the technical analysis to include these materials, this would require additional time to complete. Therefore, the staff recommends not including them as part of this rulemaking. Licensing reviews of these materials would continue using, for example, the dose based criteria of the rule as a reference, and applying on a case-by-case basis the analysis necessary to demonstrate impacts and compliance. However, it is planned that an item in the issues paper will be the materials that should be considered in the rule.

d) **Schedule of Rulemaking Steps in FY 1999**

The activities described above in Items 1a, 1b, and 1c are rulemaking-related activities that precede the actual preparation of the Federal Register (FR) notice for a proposed rule. The staff's plan and schedule for conducting these activities are shown in Attachment 3 and includes: issuing the necessary contracts as expeditiously as feasible; convening appropriate parties as part of the facilitation process for the public meetings; announcing the EIS scoping process in the FR; issuing the issues paper for public comment; and conducting four public meetings. After the public meetings, the staff will provide the Commission with a paper and briefing summarizing the results of the public meetings and indicating the next steps in the formal rulemaking process.

2. **Coordination with EPA and International Efforts**

The June 30, 1998, SRM directed the staff to notify EPA of the planned rulemaking action. The staff, in a letter from Carl Paperiello, NRC, to Lawrence Weinstock, EPA, dated August 20, 1998 (Attachment 4), described NRC's plans for rulemaking, acknowledged EPA's past work on technical underpinnings on clearance, and suggested seeking further input from EPA in an advisory capacity during NRC's rulemaking. The staff will continue to involve EPA, as well as other Federal agencies, in its rulemaking efforts through the ISCORS process and other means, as appropriate.

Currently, there are a wide variety of IAEA, EPA, and DOS efforts ongoing. One specific area involves the development of import standards for cleared materials. The clearance rulemaking activities outlined in Attachments 2 and 3 will proceed with parallel staff efforts to remain cognizant of other ongoing activities so that this information can be factored into the NRC rulemaking process.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel which has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource impacts and has no objection. The Office of the Chief Information Officer has reviewed the paper for information technology and information management implications and concurs in it.

William D. Travers
Executive Director for Operations

CONTACTS: Frank Cardile, NMSS/IMNS
(301) 415-6185
Anthony Huffert, NMSS/DWM
(301) 415-6416

Attachments:
1. SRM Dated June 30, 1998
2. Technical Basic Items Needed
3. Rulemaking Steps in FY 1999
4. Letter to EPA Dated August 20, 1998

ATTACHMENT 2

Table 1 - Technical Basis Critical Path Items Needed for a Proposed Rule

Component	Need to Satisfy	Technical Analyses Needed for EIA and RA
NEPA analysis	**10 CFR 51.70 & 51.71**	
	~ Must consider and weigh environmental impacts of proposal and alternatives	a. Individual dose factors for 4 materials (steel, Al, Cu, and concrete) - draft NUREG/CR complete 1/99
	~ Should consider technical, economic, other benefits and costs of proposal and alternatives	b. Individual dose factors for exposure to multiple sources of cleared material
	~ Should consider other interests relevant to proposal	c. Collective dose[1,2]
	~ Must quantify the factors considered	d. Calculation of costs for scenarios analyzed[1,3]
	10 CFR 51.26 - 51.29	e. Buildup of recycled material into commerce or environment[4]
	~ If EIS is prepared, use of scoping process as required in 10 CFR 51.26-29	f. Evaluation of net risks and cost-benefit of proposal and alternatives
Regulatory Analysis	~ Executive Order 12866 & 6/30/95 SRM (SECY-95-028)	g. Soil will be included using approach from cleanup rule

Draft Regulatory Guide	~ Practical implementation methods	h. Examination of economic impact (costs vs benefits) of alternatives
Public Participation	~ 6/98 SRM: Enhanced participatory process ~ 10 CFR 51.26 - 51.29, public meetings for EIS scoping process	i. Potential impact on commerce j. Analysis of survey capabilities of volumetrically contaminated equipment and material[5] k. Issues paper (draft complete 12/98) l. Public workshops

Footnotes to Table 1

1. Source term for analyzing doses and costs

Estimates of quantities and activities of equipment and material associated with clearance rulemaking alternatives (i.e., the amount of material that would be available to be cleared for different potential dose criteria (e.g., 10, 1, 0.1 mrem)) need to be developed. Previous analyses prepared in NRC contractor reports by Pacific Northwest National Lab assumed that all metals would go to low-level waste (LLW) burial and, therefore, the quantities of equipment and material per activity level were not estimated. This information will be used in analysis of clearance to estimate volumes of materials cleared at alternative dose criteria and available for potential use. As such, this information is needed to estimate population doses, non-radiological risks, and costs associated with different potential dose criteria. EPA did not estimate volumes with associated activities in its clearance analysis.

2. Collective dose/non-radiological risk calculations

- Additional scenarios for non-critical individual dose scenarios that may be important for estimating collective doses to population groups need to be developed. These scenarios need to be added into the overall analysis of collective dose; associated costs under these scenarios will have to be developed. The current NUREG/CR only deals with those groups that are limiting for individual dose, not those other groups that may also contribute to collective dose in a significant way. The experience of the cleanup rule was that additional groups should be analyzed.

- Population usage patterns for exposure to recycled/reused material to calculate exposures to populations from cleared material need to be developed. Probability of numbers of persons both processing the cleared material from scrap to manufacture and also the number of persons using the cleared material depends on the likelihood of different population groups using the material. Currently, the NUREG/CR only calculated a maximum dose assuming one particular critical group is exposed to the material.

- An evaluation of non-radiological risks associated with clearance alternatives (e.g., the more material sent to LLW, the higher the risk of non-radiological traffic fatalities from transport) needs to be included in the overall analysis of collective risks. These types of non-radiological risks were included in the GEIS for the cleanup rule (NUREG-1496), however this information has not yet been evaluated for the clearance rulemaking alternatives

3. Cost estimates

- Cost estimates need to be developed for: (a) the variety of recycle/scrap/manufacturing processes associated with clearance of materials and equipment; (b) specific actions which may occur including costs resulting from unnecessary triggering of alarms at scrap facilities, as well as other potential impacts on commerce; and (c) surveys at clearance rulemaking alternative dose criteria (information on survey costs does not presently exist at the doses being considered for clearance and for the large quantities and varied shapes of cleared material at decommissioning and during operations).

4. Buildup of material

- Collective doses and costs of recycle/scrap/manufacturing which may arise due to the buildup of recycled material into commerce or environment need to be developed.

5. As input to Regulatory Guide

- Measurement methods for low concentrations of volumetrically contaminated material that exist in various shapes and sizes need to be developed.

- Criteria for making decisions on selection of samples for surveys need to be set both for making measurements in the field and in laboratory settings.

ATTACHMENT 3

Rulemaking Steps Beginning in FY99

- Publish first part of technical analysis (draft NUREG/CR on individual dose) 1/99
- Develop additional technical basis needed to support rule (collective dose, costs, cost-benefit analysis, regulatory guidance)

- SOWs to DCPM 1/99
    - Acquire contractor support for 6/99
    - Public meetings
    - Technical analyses for EIS/RA/Reg guide
    - EIS/RA/OMB packages

- Public meeting process
    - First draft of issues paper to Steering Group 11/98 C
    - Commission paper on rule plans to EDO 1/99 C
    - Issues paper to Federal Register 3/99
    - Announce public meetings/EIS scoping in FRN 6/99
    - Conduct 4 facilitated public meetings 8/99-10/99

- Synopsis of findings:
    - Send Commission Paper on results of public meetings and Status of technical analyses to EDO