POLICY ISSUE
NOTATION VOTE

March 23, 2000 SECY-00-0070

FOR: The Commissioners

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

SUBJECT: CONTROL OF SOLID MATERIALS: RESULTS OF PUBLIC MEETINGS, STATUS OF TECHNICAL ANALYSES, AND RECOMMENDATIONS FOR PROCEEDING

PURPOSE:

To inform the Commission of results of public meetings (and written comments) on the Issues Paper on control of solid materials, the status of technical analyses supporting decision-making on this issue, and staff recommendations for proceeding.

SUMMARY:

This paper provides the Commission with information about alternatives for establishing control of solid materials and discusses issues and concerns related to the alternatives. Additionally, the paper provides a recommendation for proceeding to address control of solid materials by integrating recent Commission direction into the agency's approach.

BACKGROUND:

On June 30, 1999, the U.S. Nuclear Regulatory Commission (NRC) published, in the Federal Register (64 FR 35090), an Issues Paper indicating that the NRC was examining its approach for control of solid material. The purpose of the Issues Paper was to foster discussion about issues associated with alternative courses of action for control of solid materials at licensed facilities that have very low amounts of, or no, radioactivity. The Federal Register Notice (FRN) stated that publication of the Issues Paper was an initial step in an enhanced participatory process in which the NRC is seeking public input to its decision-making process through

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various forums, and invited written and electronic comment on the paper. To provide further opportunity for public input, the NRC held a series of public meetings during fall 1999 at four locations around the country, as announced in the FRN.

In a Staff Requirements Memorandum (SRM) dated September 20, 1999, the Commission directed the staff to prepare a paper, and brief the Commission, on: (a) stakeholder reactions and concerns with the Issues Paper expressed both at the public meetings and in written comment; (b) the status of technical analyses being done to support decision-making; and (c) recommendations on whether to proceed with rulemaking or other staff actions, regarding release of solid materials, and the schedule for future staff actions on this effort.

In an SRM dated March 8, 2000, the Commission provided further direction to the staff that it request the National Academy of Sciences (NAS) Board on Energy and Environmental Systems to conduct a study and provide recommendations on possible alternatives for release of slightly contaminated solid materials. The Commission also directed the staff to provide its recommendation on integrating the NAS study into the agency's approach for proceeding to address the control of solid materials

The staff has provided information to the public about current NRC efforts in this area. Specifically, a website dedicated to this effort was established at the following address: http://www.nrc.gov/NMSS/IMNS/controlsolids.html. The website includes the Issues Paper, other pertinent documents, and summaries of comments received to date. The website is continually updated to provide current news and information regarding upcoming meetings and other opportunities for public comment. In addition, the staff has developed a list server address through which it notifies subscribers of current activities and available documents.

The term "control of solid materials" is a general term that has been used in the Issues Paper and the public meetings on this subject; it should be noted that the international community uses the term "clearance" in referring to release of materials for unrestricted use.

DISCUSSION:

The staff has been examining process alternatives on whether criteria for control of solid materials should be established as well as technical approaches as to what the alternative might be. Both the process alternatives and technical approaches were initially discussed in the Issues Paper and much comment and additional insight about these alternatives and approaches has been obtained since the Issues Paper was published. Potential process alternatives indicated in the Issues Paper included: (a) not doing a rulemaking (either continue current practice or explore updating current guidance); or (b) proceeding to issue a proposed rule. Technical approaches would be decided upon during the conduct of a process alternative and could include: (a) permitting release of material for unrestricted use if it met certain criteria; (b) prohibiting release of material that had been in an area in a licensed facility where radioactive material was used or stored; (c) restricting release to only certain authorized uses; and (d) other approaches suggested in public comment. A discussion of the process alternatives and technical approaches is contained in Attachment 1.

In considering potential alternatives and approaches, the staff has reviewed: (a) stakeholder concerns with the Issues Paper; (b) the status of technical analyses needed to support decision-making; and (c) other important factors affecting alternatives and approaches, including ongoing international activities to develop standards and activities of other Federal agencies. Detailed discussion of public comments received, status of technical analyses, and international activities and issues, are contained in Attachments 2, 3, and 4, respectively. The following is a summary of those attachments.

Stakeholder concerns and reactions

After publication of the Issues Paper, four facilitated public meetings were held in fall 1999 in San Francisco, CA (September 15-16); Atlanta GA (October 5-6); Rockville, MD (November 1-2); and Chicago, IL (December 7-8). The agendas for the meetings consisted of sessions corresponding to the content of the Issues Paper. Attendance at the four meetings included representatives from scrap and recycling companies; steel and cement manufacturers; sanitary waste facilities; the U.S. Environmental Protection Agency (EPA); U.S. Department of Energy (DOE); U.S. Department of State (DOS); State agencies; Tribal governments; NRC licensees and licensee organizations; and the Health Physics Society. Citizen groups had expressed opposition to this process and did not attend the San Francisco and Atlanta meetings. However, a letter, signed by citizen groups, explaining why they did not attend, was delivered at these two meetings by a representative of the groups, with copies provided to attendees. Certain citizen groups did attend the Rockville and Chicago meetings, although others continued to not attend.

In addition to the public meetings, the June 30, 1999, FRN invited written and electronic public comment on the Issues Paper. The comment period was originally scheduled to end on November 15, 1999, but was extended to December 22, 1999, to accommodate a change in the original workshop schedule and to better allow stakeholders to adequately prepare for the workshop discussions. Although a number of comment letters were received requesting that the comment period be extended beyond that date, it was decided not to extend the comment period further.

There were extensive and wide-ranging comments received at the four public meetings and in the written public comments. To date, over 800 comment letters have been received on the Issues Paper. Most of these comments focused on the specific technical approach or criteria that should be developed.

Many commenters stated that there should not be release of solid materials from licensed facilities even if the calculated dose or health risks were low. In particular, potential recipients of solid material, such as scrap, metals, and cement industry representatives, objected to release of solid materials. These commenters noted that there could be a severe economic impact on their industries if consumers refused to buy products because of concerns over the presence of radioactivity. Metal industry representatives indicated that they had installed detection systems at their facilities and might reject shipments of materials released from licensed nuclear facilities even if they meet an NRC standard. A metals industry representative suggested convening a group or panel of stakeholders to work out acceptable solutions. A large number of citizen groups and individuals also expressed concern about health effects of the potential presence of this material in consumer products and indicated that NRC should prohibit the release of this material and that it should be isolated from public use. An additional suggestion made was for the identification and recapture of material

previously released from nuclear facilities.

Other commenters pointed out that there was a need for a national standard in this area because of lack of consistency in criteria and implementation. These commenters also noted that the levels discussed in the Issues Paper are in the range that scientific studies consider negligible and are a small fraction of the current NRC public health criteria in 10 CFR Part 20. With regard to an approach that would prohibit releases, nuclear industry representatives were concerned that a prohibition of this type had the potential for disrupting normal day-to-day operations and would be a significant waste of resources with no accompanying health benefit. Several commenters suggested NRC adopt the American National Standards Institute's (ANSI) N13.12 (see the discussion of other factors, below). There were comments suggesting that a broad spectrum of materials should be included in a rulemaking to cover the day-to-day decisions on materials that move into and out of licensee facilities and have either very low amounts of, or no, radioactivity.

While the Issues Paper suggested possibly restricting release of materials to only certain authorized uses as a way to keep the material out of consumer products, most commenters indicated that this approach would not work because such restrictions would be ineffective and burdensome to use. Also, it was noted that unrestricted use criteria would still be needed because restrictions would only last for the lifetime of the authorized use. The only restriction suggested as workable was to reuse or recycle the material to some other use within the nuclear industry, although some commenters suggested restricting the material to landfill sites.

Detailed discussion of stakeholder concerns and comments expressed at the public meetings and in the comment letters are presented in Attachment 2 of this paper.

Status of Technical Basis Development

The staff has continued with the development of the technical bases needed for decision-making for control of solid materials. The technical bases under development were initially described in SECY-99-028. Currently, the technical bases development includes: (a) evaluation of dose-conversion factors for individual doses; (b) estimation of collective doses, costs, and potential for multiple exposures for various alternatives; and (c) survey methods appropriate for surveying solid materials at the dose levels being considered. Complicating the technical development have been issues, raised in public comment, associated with a conflict of interest (COI) with NRC's contractor, SAIC. SAIC provided a significant portion of the technical support for this project over the past several years, including preparation of draft NUREG-1640, and was contracted to provide additional analyses to support the NRC in developing dose and cost estimates. On March 17, 2000, the staff entered into a no-cost termination settlement agreement and terminated the SAIC contract NRC-04-99-046. The staff is evaluating alternate plans for proceeding to develop technical bases. Detailed discussion of each aspect of the technical bases, including its current status, issues or problems, and future work plans, are presented in Attachment 3.

Other Factors Affecting Decision-making

There have been a variety of other activities and actions that should be considered in decision-making on control of solid materials.

Various activities are underway in the international community to set standards for control of

solid material. The European Commission is proceeding to establish new radiation protection standards, including standards for clearance. Staff has been informed that these new regulations are expected to be in place by at least two European countries by May 13, 2000. In addition, the IAEA is establishing criteria for nuclide concentrations for its member states. Development of these guidelines and criteria will have an important effect on international trade and import standards.

The EPA has responsibility for setting generally applicable environmental standards under the Atomic Energy Act (AEA). Although EPA is not pursuing a rulemaking in this area at this time, they are continuing to develop a technical data basis for estimating potential doses resulting from release of solid materials. In addition, the EPA is working with the DOS regarding the international standards setting and its relationship to import issues. The DOE, which has a large inventory of stored solid material having low amounts of radioactivity from its various defense activities, has, as of January 12, 2000, instituted a moratorium on release of metals with volumetric residual radioactivity. DOE has also established a task force to review DOE policies on release of all materials for re-use and recycling which would include public participation.

In September 1999 the American National Standards Institute (ANSI) published ANSI N13.12, "Surface and Volume Radioactivity Standards for Clearance." This standard contains criteria for unrestricted release of solid materials from nuclear facilities. 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.

Additional discussion of the ANSI standard and international activities, including their potential impact on NRC decision-making, are presented in Attachments 1 and 4, respectively.

Recommendation

The diversity of public views expressed on this issue, as well as the various actions being explored by private and public organizations, underscore the need to develop a national standard to provide a clear and uniform approach to the control of solid materials. However, the acceptability of criteria in a standard will depend on a variety of the factors described above. Thus, it is just as critical to consider the process used to move discussions forward as it is to clearly articulate the technical basis for any criteria that might be established.

Based on the above, it is the staff's recommendation that a final decision on whether to proceed with rulemaking be deferred at this time, and that the staff should take the following actions to integrate the March 8, 2000, SRM into the agency's approach for proceeding to address control of solid materials:

1) The staff will follow the direction of the March 8, 2000, SRM by requesting the NAS to conduct a study and provide recommendations on possible alternatives for release of slightly contaminated materials. In their study, NAS could consider the variety of issues and factors described above and in the Attachments to this paper as they make their recommendation. The March 8, 2000, SRM suggests that the NAS study should be completed within 9 months of initiation of the study; and

2) The staff will continue to develop the information base described in Attachment 3. Continuing these staff actions during this period will provide the staff with useful information no matter what the outcome of the NAS study. During this period the staff will develop further information on inventories of material at facilities, on potential pathways and doses (including the potential for multiple exposures), on various associated costs, and on survey methods. In addition, the staff will continue to stay informed of international initiatives in this area, related EPA and DOS activities, and the potential import and trade issues.

Conduct of the above items will allow NRC to gain further insights as to paths forward and further develop its information base. Together, they will place NRC in a better position to proceed with decisions on potential policy and technical approaches. It is planned that the staff would keep the Commission informed while the NAS study is underway and provide its recommendations as to next steps for proceeding approximately three months after completion of the NAS study.

RESOURCES

The proposed NAS study will be funded as part of the FY 2000 mid-year review. The resources for continuing to develop the information base are within current budget estimates. Resources to pursue the effort following completion of the NAS study and the Commission's decision on the alternatives to either not conduct a rulemaking or to develop a proposed rule will be considered during the FY 2002 budget formulation 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. A public announcement will be issued by the Office of Public Affairs.

William D. Travers
Executive Director
for Operations

Attachments:
1. "Analysis of Alternatives for Proceeding"
2. "Summary of Written and Public Meeting Comments"
3. "Status of Technical Basis Development"
4. "International Aspects of Clearance"

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ATTACHMENT 1

ANALYSIS OF ALTERNATIVES FOR PROCEEDING

A. INTRODUCTION

NRC is currently examining its approach for control of solid materials that have either no, or small amounts of, radioactivity at licensed facilities. This examination includes both process alternatives for establishing criteria for control of solid materials (i.e., conduct a rulemaking or not) and technical approaches for what the criteria should be (i.e., unrestricted use, prohibition, restricted use). Both the process alternatives and technical approaches were initially discussed in the Issues Paper and have been further developed to include public comment and other factors.

The analysis in this attachment is intended to provide information to facilitate decision-making regarding the process alternatives by discussing the input received at the public meetings and in written public comment, the technical bases available to support decision-making, and other important factors. The alternatives are listed and evaluated in Sections B, C, and D of this attachment.

During the course of carrying out the process alternatives, a technical approach for the actual criteria would be developed. Although it is not the intent of the analysis in this attachment to select a technical approach for control of solid material, it is instructive to discuss the approaches and describe the extensive and wide-ranging public comment received on them to date. This discussion is contained in Sections E and F of this attachment.

B. LISTING OF ALTERNATIVES

There are two broad process alternatives that the NRC could follow, i.e. to either not conduct a rulemaking, or to develop a proposed rule. These are discussed below:

1) Do not conduct a rulemaking. In this alternative the NRC would not proceed with a rulemaking at this time. Instead it could take one of the following options:

c) Continue with current case-by-case practices. In this option, the NRC would not do a rulemaking nor would it modify existing guidance. Instead it would continue to use the existing guidance contained in Regulatory Guide 1.86 and/or in other case-specific criteria, such as the detection capability of instrumentation;

d) Explore options for updating existing guidance to improve consistency of criteria. In this option, the NRC would explore options for updating existing guidance, under the existing regulatory structure of 10 CFR Part 20, to provide more uniformity in criteria. Potential updates might include defining detection limits for controlling solid materials or developing other more restrictive guidance. The extent to which guidance can be updated in the absence of a rule change may limit the extent of the guidance revision. An update to guidance would involve developing a value-impact analysis.

For either Alternative 1a or 1b, it would seem appropriate (based on the extensive input received in the Fall 1999 workshops and in written public comment) for the NRC to supplement those activities by continuing to evaluate major factors identified in the public process to date. Thus, under Alternative 1a or 1b, the staff would continue review of, for example, metals, scrap, and cement industry viewpoints, international standards setting, and other Federal agency activities. The staff would continue to conduct dose assessment studies and cost evaluations associated with control of solid material, as useful information both in current and future considerations.

2) Proceed at this time to develop a proposed rule. In this option, the NRC would proceed

toward issuance of a proposed rule establishing criteria for control of solid materials. This would involve completion of a detailed technical database on dose and cost analyses and on survey methods and completion of a Generic Environmental Impact Statement (GEIS) and Regulatory Impact Analysis (RIA) to support decision-making for the propose rule. This would also involve resolving the wide range of public comments received at the public workshops and in written comment, including resolving issues raised by scrap, metal and cement industries representatives, citizen groups, licensees and licensee organizations, States, individuals, and others. It would also involve considering other major factors, including the international initiatives and the ANSI N13.12 standard.

C. BASES FOR EVALUATION OF ALTERNATIVES

The process alternatives are evaluated based on the following factors, which address the directions provided by the Commission in the September 20, 1999, SRM:

e) Stakeholder concerns and reactions. There were extensive and strong stakeholder views expressed on a broad range of issues associated with control of solid materials. More detail on stakeholder concerns are discussed below and in Attachment 2 of this paper;

f) Technical analyses needed for each alternative. There is significant work that has been done and still needs to be done to support decision-making. More detail on technical analyses are discussed below and in Attachment 3 of this paper;

g) The schedule for each alternative. The schedule for a particular alternative depends on the extent of the technical analysis needed. This is discussed for each of the alternatives in Section D;

h) In addition, the staff has also evaluated the alternatives based on consideration of other important factors which can affect decision-making. These include:

a) Ongoing International activities to develop standards.

The European Commission is proceeding to establish new radiation protection standards, including standards for clearance (unrestricted use). Staff has been informed that these new regulations are expected to be in place by at least two European countries by May 13, 2000.

In addition, the IAEA is establishing criteria for nuclide concentrations for its member states. Development of these guidelines and criteria will have an important effect on international trade and import standards. In particular, U.S. standards different from international standards could cause import/export problems. A more detailed discussion of international activities in this area is contained in Attachment 4.

b) Activities of other Federal agencies.

The U.S. Environmental Protection Agency (EPA) has responsibility for setting generally applicable environmental standards under the AEA. Although EPA is not pursuing a rulemaking in this area at this time, they are continuing to develop a technical data basis for estimating potential doses resulting from release of solid materials. In addition, the EPA is working with the U.S. Department of State regarding the international standards setting and related import and trade issues. A more detailed discussion of how EPA activities relate to international activities in this area is discussed in Attachment 4 of this paper.

The U.S. Department of Energy (DOE), which has a large inventory of stored solid material having low amounts of radioactivity from its various defense activities, has, as of January 12, 2000, instituted a moratorium on release of metals with volumetric residual radioactivity. DOE has also formed a task force to review DOE policies on release of all materials for re-use and recycling which would include public participation.

c) National standards-setting bodies.

In September 1999, the American National Standards Institute (ANSI) published ANSI N13.12, "Surface and Volume Radioactivity Standards for Clearance." This standard applies to material and equipment released from controlled areas during operations and contains a radiation dose criterion of 1 mrem/yr, as well as derived screening levels for surface and volume contamination for groups of radionuclides (this is referred to in the standard as "clearance"). The standard is not intended to be a criterion for use during decommissioning or for the release of land or soil intended for agricultural purposes. 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. If the standard were to be used as the basis for a rulemaking, NRC would have to evaluate it as part of an Administrative Procedures Act (APA) process, including conducting a NEPA analysis in a GEIS and a RIA. NRC would also need to consider its consistency with U.S. and international studies and associated implementation issues. In addition, many of the public comments received on the Issues Paper would have to be considered in evaluating use of the ANSI N13.12.

D. EVALUATION OF ALTERNATIVES

1) ALTERNATIVE 1: DO NOT CONDUCT A RULEMAKING. Under this alternative, NRC would not proceed with a rulemaking at this time. Instead it could take one of the following options: (a) continue with its current case-specific criteria or (b) explore options for updating existing guidance to improve consistency of criteria.

These alternatives were initially presented in the Issues Paper. However, based on the extensive discussions at the workshops and public comment received, if either Alternative 1a or 1b is selected, NRC could supplement those activities by maintaining an ongoing participation in various areas to evaluate major factors identified in the public comments to date that could affect its future decision-making in this area. This would include following other initiatives and addressing complicated issues including: (a) maintaining a dialogue with a broad spectrum of stakeholders, such as steel, scrap, and cement industry representatives, landfill representatives and public interest groups, to develop acceptable approaches for solid material usage; and (b) following international developments in setting standards and EPA actions taken in response to those developments, in particular with regard to its responsibilities in the area of import standards. In addition, the staff could continue its review of draft NUREG-1640 as discussed in Attachment 3 and conduct dose assessment studies and cost evaluations associated with control of solid material, as appropriate. Based on the outcome of these actions, NRC could further evaluate its alternatives for proceeding. A schedule is not established at this time for these activities.

The alternatives are discussed below.

ALTERNATIVE 1a: DO NOT CONDUCT A RULEMAKING AND CONTINUE CURRENT PRACTICE. Under this alternative, no NRC rule would be prepared and NRC would continue its use of existing guidance. Licensees would still continue to seek release of solid materials, and NRC would continue to evaluate these requests on a case-by case basis using existing guidance, license conditions, policies, etc.

a) Public comment.

There were some comments that favored continuing the current case-specific approach of using existing guidance because it is considered health protective and there is common understanding on how to implement it.

However, other comments noted problems with continued use of current practice and cited the need for a national standard. Reasons given were that the current case-by-case approach can be cumbersome, time-consuming, and result in inconsistent implementation. It was indicated that a national standard that is technically defensible, safe, and could be readily implemented would improve consistency. Some commenters objected to the current approach because it permits material to be released on a case-by-case basis.

A number of comments were received in which the commenters objected to NRC conducting a rulemaking because they felt that a rule would permit release of material into consumer products.
For a more detailed discussion of the public comments on this alternative, see Attachment #2.

(b) Technical analyses needed for this alternative.

If NRC were to continue with current practice (not do a rulemaking nor update its guidance), no additional technical analyses to support an GEIS or RIA would be needed to support current practice.

However, as noted above, NRC may choose to maintain an ongoing participation in various areas to evaluate major factors and conduct further technical analyses.

(c) The schedule for this alternative.

If NRC continued current practice (not do a rulemaking), the alternative is essentially in place at this time.

(d) Other significant factors affecting decision-making.

If NRC continued current practice (not do a rulemaking), it would have to be aware of potential international standards being developed, as well as consistency with the consensus standard developed by ANSI.

(e) Analysis of alternative.

An advantage of continuing current practice would be that it could permit NRC to continue its licensing activities with less impact on staff resources than conducting rulemaking and the impact to licensees compared to other options would be minimal. It would also allow NRC to consider other U.S. and international initiatives in this area and perhaps develop additional consensus for proceeding. A disadvantage of this alternative is that there would continue to be problems of consistency and the criteria would be incomplete regarding volumetrically contaminated materials. In addition, this alternative would not respond to concerns that material is currently being released using existing guidance. Also, licensees may be impacted if the metals industry (which has indicated that radiation detectors installed at their plants will alarm at Regulatory Guide 1.86 levels) reject such shipments.

ALTERNATIVE 1b: DO NOT CONDUCT A RULEMAKING AND EXPLORE OPTIONS FOR UPDATING EXISTING GUIDANCE TO IMPROVE CONSISTENCY OF CRITERIA.

In this option, NRC would explore options for updating existing guidance under the existing regulatory structure of 10 CFR Part 20 to provide more uniformity in criteria. Potential updates might include defining detection limits for controlling solid materials or developing other more restrictive guidance. The extent to which guidance can be updated in the absence of a rule change may limit the extent of the guidance revision. An update to guidance would involve developing a value-impact analysis.

(a) Public comment.

Little comment was focused specifically on this alternative. However, many of the comments received on Alternative 1a are also applicable to this alternative, including comments about continuing current practices, the need for consistency of approach and implementation, concerns from stakeholders about potential economic impacts, and international considerations.

(b) Technical analyses needed for this alternative.

One approach would be to update guidance based on the existing non-detectability criteria already in use by certain NRC licensees. The technical analysis needed to support this could be relatively straightforward. A different approach would be to update levels of detectability based on more current information. This would involve an evaluation of state-of-the-art levels of detection and therefore the level of technical analyses would be more complex. NRC would also have to reevaluate its technical basis periodically because detection capability changes over time as instrumentation advances. Also, if volumetric levels of detection were established, this would involve a comprehensive analysis similar to that needed to support a rule. Analyses would need to be conducted to develop a value impact analysis to support the updated guidance.

(c) The schedule for this alternative.

If updated guidance used the existing NRC non-detectability criteria, preparation of the

guidance should be relatively straight-forward. However, there could be significant concerns and issues raised about updating this guidance that would require resolution. If the guidance contained updated detection levels or other new criteria, development of a guide would require additional technical analyses to support the changes. For any of these options, it would have to be determined whether the updates could be done within the existing regulatory framework without rulemaking. Also, the staff would have to explore ways of applying updated guidance in light of the fact that many materials licensees have license conditions which reflect older guidance. A schedule has not been established at this time, but would be developed if this alternative is taken.

(d) Other significant factors affecting this alternative.

If NRC updated its guidance, the staff would maintain cognizance of related activities so as to minimize inconsistencies with any international standards or EPA standards developed, as well as with the consensus standard developed by ANSI.

(e) Analysis of alternative.

An advantage of updating guidance is that it would simplify most current case-by-case problems so that reviews and licensing could be done in a more structured, consistent, and implementable manner without waiting for rulemaking to take place or expending staff resources for rulemaking. In addition, if a new detectability criteria was developed, it would be based on more recent detectability information. A disadvantage of updating a guide based on detection capability is that it would not be consistent with risk-informed regulatory principles. Also, the extent to which a guide could be updated without rulemaking could be limited, and the time involved and impact on licensees could be significant and similar to that for rulemaking. In addition, there could still be issues regarding consistency and stakeholder concerns (including metals industry concerns), and a need for volumetric criteria, which would have to be addressed. NRC would also have to reevaluate its technical basis periodically because detection capability changes over time as instrumentation advances.

ALTERNATIVE 2: PROCEED AT THIS TIME TO DEVELOP A PROPOSED RULE. In this option, NRC would proceed towards issuance of a proposed rule in Part 20 establishing criteria for control of solid materials. There are technical approaches under this alternative that would have to be decided upon during the rulemaking process. These include those discussed in the Issues Paper and listed in Section E of this attachment. To support decision-making regarding these approaches, NRC would develop a GEIS and an analysis of costs and benefits in a RIA. To support these decision-making tools, NRC would develop a detailed technical analysis, including inventory of materials at licensed facilities, dose assessment (including evaluation of potential for multiple exposures), costs, and methods of implementation. These analyses are discussed further in Attachment 3. The staff would also need to maintain cognizance of other scientific studies being conducted and other major factors affecting decision-making. In addition, the rulemaking would also need to consider public comments made at the workshops and in written comment. This would likely involve significant staff efforts at resolving the comments and reconciling them.

a) Public comment on this alternative.

Many of the comments received were similar to those discussed above, namely that there is a need for a national standard which could be developed in a rulemaking. Other commenters indicated that they were concerned that issuance of a rule would result in legalization of release of materials.

In addition, comments were raised that a group or panel of major stakeholders be allowed to come together and work out acceptable solutions which they would then pass on to the Commission to act on. This panel would address major factors affecting decision-making in this

area.

With regard to the four technical approaches as to what the criteria should be, there was extensive and diverse public comment. These comments are discussed below in Section F of this attachment, and as noted above are important to consider in deciding upon a process alternative.

For a more detailed discussion of the public comments on this alternative, see Attachment #2.

(b) Technical analyses needed for this alternative.

If NRC does a rulemaking, substantial additional analyses of dose assessments and cost evaluations are needed to support decision-making. The amount and nature of the analyses for any of the approaches (unrestricted, restricted, or prohibition) is the same.

Complicating the technical development are issues, raised in public comment, associated with a conflict of interest (COI) with NRC's contractor that prepared draft NUREG-1640 and that it had planned to use to develop the dose and cost bases for the GEIS and RIA. On March 17, 2000, the staff entered into a no-cost termination settlement agreement and terminated the contract. The staff is evaluating alternate plans for proceeding to develop technical bases. This is discussed further in Attachment 3 of this paper.

As noted in Section C of this attachment, both the international community and the EPA have developed technical bases to support standards setting in this area. Some combination of NRC analyses and use of the international or EPA technical information might be useful as support for rulemaking.

(c) The schedule for this alternative.

If NRC were to a do a rulemaking, the staff's original estimate of the schedule for developing a proposed rule in 2001 is no longer applicable due to the termination of the technical basis contract. This matter is discussed further in Attachment 3 of this paper. An approach that would minimize the impact on the schedule is the presence of other sources of information in this area that could be used to support decision-making, including international or EPA technical bases. Even though this information could be available in the near future, it would need to be reviewed by the staff and the scope of those studies might only have limited applicability. Therefore, use of these bases may not significantly accelerate the schedule.

If a restricted use approach is used whereby the material is restricted to the licensed nuclear industry, a rulemaking may not be necessary because such activities may fit under existing transfer rules.

(d) Other significant factors affecting decision-making.

A rulemaking would have to consider the consistency of its criteria with various other initiatives that are ongoing. For example, if a rule was adopted in the U.S. that was different from international standards, this could cause import/export issues. Another consideration is that the EPA has responsibility for setting generally applicable environmental standards. Although EPA does not currently have a rulemaking in progress in this area, they are continuing to develop a technical basis for estimating potential doses resulting from release of solid materials. In addition, the EPA is working with the U.S. Department of State regarding the international standards setting which could potentially have an effect on import standards. A rulemaking would also have to address its relationship to ANSI N13.12, namely whether it was being used and if not, the basis for not using it.

Based on the public workshops and written comment to date, a rulemaking would have to consider potential impacts of concerns of those organizations which would potentially receive

material released from licensed facilities. These would include the metals, scrap, and concrete industries, and landfill operators. In comment to date, the metals industries have indicated that they would potentially reject material released under an NRC standard developed in rulemaking.

(e) Analysis of this alternative.

An advantage of proceeding at this time to develop a proposed rule is that it would establish a national standard based on a full evaluation of health and environmental impacts and cost-benefit analyses of, and public comment on, various courses of action. Given the wide diversity of views about different potential technical approaches (see Sections E and F of this attachment), a national standard for the control of solid materials established through the full Administrative Procedures Act process would be the best means for establishing such criteria. Proceeding with a proposed rule would also allow the NRC to factor into the national standard other ongoing initiatives, including those international organizations, other Federal agencies, and other standards setting and consensus organizations.

A disadvantage of proceeding to develop a proposed rule at this time is that the strong and varied comments that have been received to date will require significant effort to resolve. Criteria developed in a rulemaking may be difficult to establish and implement because of the controversy demonstrated in the workshops and written comment, as well the recent significant Congressional interest. In particular, a group that could be impacted by a standard set by rulemaking is the metal and concrete industries, which would potentially receive material released from licensed facilities. Representatives of these industries have indicated that solid materials released under an NRC standard might be rejected at their facilities. In addition, completion of the technical bases development, irrespective of which technical approach is selected, will require significant staff resources, and may be more difficult than customary at this time because of the controversies surrounding this effort. Even if use is made of a consensus standard such as ANSI N13.12, staff resources to adopt the standard as basis for rulemaking could be significant and the standard would be subject to the same comment noted here.

E. DISCUSSION OF TECHNICAL APPROACHES

During the course of carrying out the process alternatives, a technical approach for the actual criteria would be developed. Potential technical approaches were initially described in the Issues Paper and have engendered significant public comment. Although it is not the intent of the analysis in this attachment to select a technical approach for control of solid material, it is instructive to discuss the approaches and describe the extensive and wide-ranging public comment received on them to date. The potential technical approaches are:

1) **Release of solid materials for unrestricted use.** In this approach, material meeting a standard established by regulation could be released for any public use (the international community uses the term “clearance” in referring to release of materials for unrestricted use). As discussed in the Issues Paper, a rule might potentially either be: (i) dose-based in the range of 0.001, 0.01, or 0.1 mSv/yr (0.1, 1, or 10 mrem/yr); or (ii) detection-based using a criterion of no dose above background. In establishing a standard, the NRC could adopt the ANSI N13.12 standard (see Section D.4.c). NRC could also institute a tracking system on material released;

2) **Prohibition of release.** In this approach, solid material that has been in an area in a licensed facility where radioactive material has been used or stored would not be released but would be sent to a licensed low-level waste (LLW) disposal facility. An additional suggestion made in the public meetings was also the recapture of material previously released from nuclear facilities;

3) **Restrict release to certain authorized uses.** In this approach, material would be restricted to only certain authorized uses such as either: (i) some non-licensed use (e.g., bridge supports, public landfills); or (ii) within the nuclear industry (e.g., shipping casks). A restriction to within the licensed industry may be considered consistent with existing transfer requirements under a license and not require a rulemaking;

4) **Segregate requirements based on type of material involved.** This approach would involve some combination of 1, 2, or 3, above. For example, certain materials might be permitted to be released for unrestricted use, whereas public use of other materials might be prohibited or restricted. A challenge under this option would be determining what criteria to use for making this distinction.

F. ASSESSMENT OF TECHNICAL APPROACHES

The technical approaches noted in Section E would be decided upon during the conduct of a process alternative. Although it is not the intent of this attachment to select one of these technical approaches, the wide ranging concerns and issues raised in public comment regarding these technical approaches are important to consider when considering the process alternatives. A summary of the comments includes the following:

1) Unrestricted release. Comments on this approach were sharply divergent.

Many commenters opposed unrestricted release of materials. Representatives of scrap and metal industries strongly objected to permitting unrestricted release of solid materials and noted that there could be a severe economic impact on their industries if consumers refused to buy products because of their concerns over presence of radioactivity in the products. The metal industry representatives indicated that they had installed detection systems at their facilities and might reject shipments of materials released from licensed nuclear facilities even if they meet an NRC standard. Cement industry representation also objected to this approach. Citizens groups and individuals expressed strong concerns over health risks associated with having radioactive material in consumer products.

Other commenters pointed out that, because of lack of consistency in criteria and implementation, there was a need for a national dose-based standard in this area. These commenters also noted that the potential levels for unrestricted use discussed in the Issues Paper are in the range that scientific studies consider negligible and are a small fraction of the current NRC public health criteria in 10 CFR Part 20. It was noted that the levels would also be consistent with those being considered by international scientific organizations. The Health Physics Society noted that it has a position paper supporting ANSI N13.12 and suggested NRC consider adopting the ANSI standard. Comments were also made suggesting that a wide scope of materials should be included in a rulemaking in order to cover the day-to-day decisions on

materials that have either very low amounts of, or no, radioactivity that move into and out of licensee facilities.

2) Prohibition of release. Many commenters who opposed unrestricted use, favored prohibiting the release of solid materials that had been in radioactive areas at nuclear facilities and isolating this material thus removing the potential for materials to end up in consumer goods. Nuclear industry representatives were very concerned that a prohibition of this type had the potential for disrupting normal day-to-day operations and could result in sending material at very low dose levels to a licensed LLW disposal facility.

A number of commenters favoring prohibition also indicated that NRC should recapture materials which it has permitted to be released using current case-by-case criteria.

3) Restricted use. Some commenters suggested possibly restricting release of materials to only certain authorized uses as a way to keep the material out of consumer products. However, a number of commenters were concerned that this approach would not work because such restrictions would be ineffective. The only restriction suggested as workable was to reuse or recycle the material to some other use within the nuclear industry. One commenter suggested that an approach limiting restrictions to within the nuclear industry might not require a rulemaking because of existing license transfer rules.

Other commenters noted that an unrestricted use criterion would still be needed because, even with restrictions on use, the material will ultimately be released for unrestricted use after the lifetime of the restriction is over.

4) Segregate requirements based on type of material involved. Comments were also received which suggested a standard that would have segregated criteria for different materials. Some commenters, in noting that much of the material requiring disposition is non-metal (trash, soils, medical wastes, short-lived materials, etc) and that materials are routinely segregated at a licensed facility, suggested having separate requirements for metals would be appropriate. It was suggested that this approach could allow licensees to handle disposition of certain materials without waiting for rulemaking for all materials to be completed and could allow a phased implementation of criteria which could function as a pilot program.

ATTACHMENT 2

SUMMARY OF WRITTEN AND PUBLIC MEETING COMMENTS

A. PURPOSE

The purpose of this attachment is to provide a summary of the comments received both at the four public workshops and in written comments in response to the Issues Paper.

B. INTRODUCTION

As part of the Nuclear Regulatory Commission's (NRC's) examination of its approach for control of solid materials, the NRC sought early public input on the major issues associated with this effort, including conducting a scoping process related to associated environmental impacts. To aid in this process, the NRC prepared an Issues Paper that describes issues and alternatives related to release of solid materials. The purpose of the Issues Paper was to foster discussion about issues associated with alternative courses of action for control of solid materials at licensed facilities that have very low amounts of, or no, radioactivity.

This Issues Paper was published in the Federal Register on June 30, 1999. The closing period for public comments was originally November 15, 1999, but was extended until December 22, 1999. The Federal Register Notice (FRN) invited public comment on the paper and, to provide further opportunity for public input, the NRC held a series of public meetings during fall 1999 at the following four locations:

1) San Francisco, CA on September 15 -16, 1999
2) Atlanta, GA on October 5-6, 1999
3) Rockville, MD on November 1-2, 1999
4) Chicago, IL on December 7-8, 1999

The Issues Paper described the following process alternatives:

- Continue current NRC practice of case-by case consideration of licensee requests for release of solid material or consider updating existing guidance;
- Conduct a rulemaking to establish criteria for control of solid materials.

The Issues Paper indicated that a rulemaking could have three technical approaches:

1. Permit release of solid materials for unrestricted use if the potential doses to the public from unrestricted use of the material were less than a specified level determined during the rulemaking process;
2. Restrict release of solid materials to only certain authorized uses;
3. Do not permit either unrestricted or restricted release of solid material that has been in an area where radioactive material has been used or stored, and instead require all such materials to go to a licensed low-level waste (LLW) disposal facility. This is referred to as prohibition.

Over 800 comments have been received on the Issues Paper. The majority of the comments focused on the specific technical approaches. With the assistance of contractors, the public meeting transcripts and the public comments received by the NRC staff were collected and organized into a database to facilitate NRC staff review of the public comment. The following provides a summary of the public comments and meetings, as well as major trends in the comments. It is anticipated that a more detailed characterization and summary of the comments will be published in a NUREG report and be available on the NRC's website on control of solid materials.

Sections C and D summarize comments received on the process alternatives for establishing criteria for control of solid material (Section C summarizes comments on whether to continue

the current case-by-case approach or update that approach, and Section D summarizes comments on whether to conduct a rulemaking). Sections E, F, G, and H summarize comments on the technical approaches as to what the criteria should be. Sections I, J, K, and L summarize comments on development of NRC's technical information base, other procedural issues, international issues, and materials that should be considered, respectively.

C. PROCESS ALTERNATIVE - CONTINUE CURRENT PRACTICE OR UPDATE GUIDANCE

Comments on the process alternative of continuing current approach or updating guidance included the following:

1. Advantages of continuing current approach

Some comments favored continuing the current practice of using Regulatory Guide (RG) 1.86. Comments included:

a) It has been a useful tool for 20 years;
b) It is health protective;
c) There is common understanding as to how to use it.

2. Advantages of revising or updating the current approach

Some commenters suggested that it would be advantageous to make improvements in the current case-by-case approach. These included:

a) Consider a graded approach of retaining elements of RG 1.86;
b) Produce a multi-agency guide based on risk/dose considerations that provides acceptable methods for decision-makers to make case-by-case determinations;
c) Update guidance with specific contamination limits which are dose-based rather than detection-based for different geometries and nuclides;
d) Specify material and release scenarios to be addressed and develop realistic guidance on codes to be used in case-by-case analysis;
e) Allow a case-by-case approach because of the importance and diversity of clearance decisions;
f) Reevaluate tables in 10 CFR 20 on exempt concentrations and quantities to set volumetric criteria for small amounts of material;
g) Review RG 1.86 to assess whether levels in it are adequately protective and revise as necessary.

3. Disadvantages of continuing current approach

Some commenters noted problems with use of current practice in their day-to-day operations. Comments included:

a) It does not provide an adequate or logical regulatory framework, does not provide clear guidance, causes each case to repeat previous efforts, and is not cost effective;
b) Without clear guidance some material is currently disposed of as radioactive waste even though there is not enough radioactive material to cause an exposure. This is an inappropriate use of resources;
c) It can be a difficult process and takes a lot of staff time for States. It can also entail redundancy of oversight between the NRC and State agencies;
d) It is inconsistent (fluctuations in background, geometry changes, slight differences in detection levels between instruments), slow, resource intensive, and can be difficult to implement, and can cause questions;
e) The no-detection policy can cause problems and is inconsistent with State direction and international initiatives. There can be inconsistencies in cases where "non-detectable" could be detectable because it depends on the measurement technology used;

f) Volumetric contamination is not considered;
g) Cumulative impacts are not considered;
h) RG 1.86 is based on instrument detection rather than dose and does not apply to all nuclides;
i) RG 1.86 should not continue to be used as a long term solution;
j) Materials need to be released from facilities each day (and more material will be available for release in the future because of decommissionings) and improved decision criteria are needed about what should be done with these materials.

Other commenters indicated that they oppose the use of current practice to allow release of material under any circumstance. Comments included:

a) Current practices of release of materials based on case-by-case considerations under RG 1.86 should cease;
b) RG 1.86 is out of date and should not be updated or used because it lacks the full force and legitimacy of a final rule done under the Administrative Procedures Act (APA);
c) RG 1.86 was developed based on criteria for decontamination of buildings and not for releasing materials involving intimate public contact. RG 1.86 should not be misused to allow releases into the marketplace or converted to dose basis;
d) RG 1.86 should be removed from licenses so that licensees cannot release radioactive wastes into garbage for landfills or the marketplace;
e) There is no proof that what has been released so far has not harmed the public and there is no data on effects of material released so far;
f) There must be warning labels at a minimum so these products could be avoided.

D. PROCESS ALTERNATIVE - SHOULD NRC DO A RULEMAKING

Comments were received on the process alternative of whether NRC should do a rulemaking. These are summarized here. A number of comments focused on specific technical approaches and these are discussed in Sections E, F, G, and H of this attachment.

1. Advantages of a rulemaking

a) A national standard that provides consistency of standards, is technically defensible and safe, and can be readily implemented, would be useful;
b) A dose-based standard is needed;
c) A national standard is needed because standards in various States are different around the country;
d) It could provide an appropriate scientific basis for consistent regulations;
e) It would be cost effective compared to the status quo;
f) It could increase public confidence because the standard would be clear as to safety;
g) It would provide a standard indicating that any material released is clean and safe;
h) It would reduce unnecessary regulatory burden;
i) It would be supportive of international initiatives.

2. Disadvantages of a rulemaking

a) A rulemaking would permit release of waste material into consumer products and radioactivity at any level is not acceptable;
b) A rulemaking would put standards in place for release that would expand the amount of material the public is exposed to;
c) A rule would only benefit the licensees and there would be no benefit to the general public;
d) It would not be practical;
e) Past failures by NRC in keeping radioactive materials from being improperly released

argue against having a release rule;

f) The cost of analysis and regulatory approval is too great;

g) Volumetric monitoring methods are not perfected.

E. TECHNICAL APPROACH - UNRESTRICTED RELEASE OF SOLID MATERIALS

In general, comments in this area fell into distinct viewpoints by stakeholder grouping. Therefore for ease of following the nature of comments this section is arranged by stakeholder group. Specific stakeholder categories and comments include:

1. Metals industry

Metals producers indicated that they were opposed to unrestricted release of metals that could come to their facilities for potential recycle and suggested that they would support the following approach for control of solid materials.

- Metal could be released solely for specific restricted applications that would preclude its being scrapped, melted and recycled for use in consumer or commercial products. The specified restricted applications would limit the metal to serving a nuclear related purpose, i.e., materials that are to be used for their original purpose offsite could be released without special restrictions.

- Metal could be released for disposal in municipal or industrial landfills or it could be processed at a dedicated licensed facility where metal would be recycled for use only at a NRC licensed nuclear facility or a Department of Energy (DOE) facility. Material would need to comply with labeling and tracking requirements, but tracking would end once metal arrives at a landfill or the dedicated licensed facility. The output of a processing facility would have to be tracked to ensure that it winds up at an NRC licensed or DOE operated facility.

- If metal can be reasonably shown to have not been radioactively contaminated in the licensed facility and if radiation detectors are set to detect above-background levels of radiation, then the metal could be released for unrestricted use if it does not contain above-background levels. This metal must be subject to labeling and tracking requirements so that a facility that gets it will be advised of its origin so they can make an informed decision about whether to accept it.

Written comments were also provided by the scrap metal industry. Their comments noted that the following issues need to be clarified before an effective rulemaking can be undertaken:

- There is probably a substantial amount of material at licensed facilities that has never become contaminated with radioactive material. While this material could be recycled, all affected stakeholders would need to agree on a measurable definition and acceptable means for proving and documenting that such material did not become contaminated by radioactive material and that the material did not become mixed with contaminated material at any time prior to release.

- Any new regulation for the release of material that is contaminated at low levels must be based on both current detection capability and criteria acceptable to affected stakeholders. Before criteria could be established, stakeholders would have to review several issues, including: (a) the effect of contamination on employees and equipment; (b) the capability to detect radioactivity in material; (c) potential uses of recycled material and acceptable by affected industries and the general public of this material; and (d) the potential to assure that such material could be used only for the purposes acceptable to the affected industries and the general public.

Comments from the metals industry in support of their position included the following:

a) Health/environmental considerations

(1) Loss of control of orphan sources and illicit trafficking present potential worker exposure problems;
(2) There would be little environmental benefit of recycling of metals from licensed facilities because the amount of such metal is small compared to the total feedstock and the impact would be less than 1% per year and would not affect the amount of mining conducted.

b) Cost-benefit considerations

(1) Recycling of metal from licensed facilities undermines public trust in the safety of consumer products. Perhaps safe levels can be set, however the marketability of products will be set by public perception and it is unlikely that the public will accept products that they use each day containing what will be characterized in media as "radioactive material." There is a sense of risk from uncertainty and the public will feel that any risk is not worth it no matter how low a standard is set, and will not trust government to tell them what is safe;
(2) There could be a very large economic impact on steel industries because consumers (who are their customers) do not want products because of concerns, even if only perceived, over presence of radiation and will de-select products. Such impacts could include loss of revenue and jobs if customers refuse to buy products made with metals. The resulting impact on the steel industry could be as high as $600 million even if there was only a 1% reduction in purchases;
(3) The issue and problem of what to do with this material should not be shifted to the commercial metals industry but rather dealt with at the source by the generators of the material;
(4) The amount of recycled steel from NRC-licensed facilities is so small that the economic advantage of recycling it is small;
(5) The history of problems with loss of control of orphan sources has resulted in significant decontamination costs at steel mills;
(6) Public perception could influence industry to mine more virgin ore to vouchsafe that metals used in consumer products do not contain radioactive materials.

c) Issues on the ability to track/trace material

(1) it is not clear that the necessary controls can be put into place to monitor and track material released from licensed facilities, and, therefore, it cannot be assured that the steel industry will not be burdened with material with higher levels of contamination.

d) Potential for rejection of incoming material at facilities receiving material

(1) The steel industry would likely reject shipments of material released from NRC licensees even under an NRC standard;
(2) Detectors at steel mills are set at low dose rates that will alarm at levels near a NRC standard that might be promulgated (these detection systems are used because of previous problems with orphan sources). Steel and scrap yard detectors are becoming even more sensitive. The metals industry does not have the capability to distinguish the source of the alarm;
(3) Metals industry cannot take the financial liability of allowing radioactive material into their mills and exposing individuals and incurring economic loss.

2. Citizen groups and individuals

These commenters generally indicated that they were opposed to releasing materials for unrestricted release. Comments included:

a) Health/risk considerations

(1) The risks being considered here are avoidable, involuntary, and unnecessary (unlike the dose a person gets from medical treatments), even if they are small;
(2) These risks are long term risks and it is not known what the risk would be to future generations, including genetics and reproductive capabilities. Also, analyses won't be able to determine the total dose, cumulative effects, or effects to children or people working with the materials;
(3) Computer models can't accurately predict all doses to the public and projections of reasonable/acceptable risks are meaningless;
(4) No dose above background is acceptable. Every exposure increases chance of cancer;
(5) Even a risk of 4 in 10,000 is too high, especially when projected over the U.S. population;
(6) The fact that we receive a dose from background doesn't justify adding more dose even if it is less than background;
(7) Analyses won't be able to determine interrelationships between dose and other hazardous impacts;
(8) The fact that there are air and liquid emission standards does not justify allowing more releases of solids into consumer products;
(9) Releases of solid materials will expose workers at scrap metal facilities to potentially significant levels of contamination;
(10) Because material is released now is not a justification for releasing more material;
(11) Any standard that would release contaminated materials would not protect public health and safety.

b) Consumer products/isolation issues

(1) introduction of radioactive waste materials into the public's consumer products (in particular products in the home) poses unnecessary risks to the public and the potential for multiple exposures;
(2) There are no direct benefits from releasing materials to the public;
(3) Radioactive waste should be isolated from the public domain;
(4) Labels would be needed to identify products made from released material otherwise people would be exposed without any warning.

c) Cost-benefit and liability considerations

(1) There would not be any clear liability as to who is responsible for materials released once they have gotten into the public sector;
(2) NRC should not transfer the problem of what to do with this material by passing the problem to scrap dealers and steel manufacturers;
(3) A rule is just an economic aid to nuclear industry.

d) Issues with ability to track/trace material

(1) NRC will not be able to measure releases accurately or enforce criteria because monitoring to assure compliance is difficult and hot spots could be missed;
(2) Given the uncertainty of instrumentation at low levels of dose near background, material would not be able to be safely controlled at its source;
(3) Released material can't be tracked. A person could be exposed to many items because

once the material is released it will not be controlled;
(4) Improper releases cannot be avoided.

e) Lack of trust issues

(1) Licensees and DOE cannot be trusted. Because workers have been misled about radiation hazards in the past and because other rules have not always been followed, it is not clear if a rule in this area would be followed;
(2) NRC has failed on the orphan source problem and there is no reason to believe that more problems would not occur here;
(3) Workers at licensed facilities can't be trusted to detect radiation in releases when it may not be in the best economic interests of the licensee;
(4) There have been unreported releases at NRC licensed facilities and NRC must fully disclose all metals that have been released and are currently in consumer products.

3. Cement industry

The cement industry indicated that they were opposed to release of concrete for unrestricted uses that could come to their facilities for potential recycle. Comments included:

a) Health/risk considerations

(1) Public exposure to products made with concrete is high, including use of concrete in drinking water reservoirs, tanks, and pipes, in residences, schools, and office buildings, and in driveways, sidewalks, and train stations, etc. In addition, there can be exposures to concrete masons in the concrete industry;
(2) Acceptance of radioactive material has no benefit to the cement and concrete industry but only possible endangerment to the industry's workers and customers;
(3) Exposures from other solid materials would add to potential radioactive doses from concrete products;
(4) Preventing additional exposure to the public from man-made sources in consumer goods is in the best interest of the public and should be NRC's primary activity in carrying out its Congressional mandate to protect public health and safety.

b) Cost-benefit considerations

(1) Any real or perceived public health risks posed by radioactive consumer goods, regardless of how slight the risk is, will not be tolerated by consumers who will not find the benefits of recycling by release of solid material from NRC licensees into commerce as persuasive reasons to accept the perceived additional exposures. These consumers will decide not to purchase these goods which will translate into loss of market for the cement and concrete industries;
(2) Increased potential for the release of radioactive material for reuse in the cement and concrete industry will cause them to incur significant additional expenses for surveillance for incoming radioactive material as well as management of any radioactive materials. Cement companies do not have the instruments and personnel training necessary to do these screenings and the industry would incur significant expenses for purchase of radioactivity monitoring equipment, training for personnel. In addition, there would be facility modifications to segregate material, disposal costs for "orphan" radioactive material, liability insurance, and legal costs;
(3) A rulemaking will effectively shift the economic burden of disposal of the solid materials from the NRC licensees to the industries that would receive these wastes as recyclable material. This appears unfair considering that the licensees profited from the producing

of these wastes;

(4) The economic value for used concrete used as a fill material for aggregate is very low compared to virgin materials;

(5) NRC should practice gaining the public's trust on issues where the potential adverse economic effects are limited to its licensees' businesses before attempting a rulemaking that could have adverse economic effects on businesses outside of the licensees.

c) Potential for rejection of incoming material at facilities receiving material

(1) Concrete dealers might begin to use detectors for screening because it is likely they will have similar concerns as steel manufacturers regarding consumer unwillingness to purchase their products if there are concerns about the products containing radioactivity.

d) Other

(1) With regard to the use of fly ash in concrete products (fly ash is a technically enhanced naturally occurring material; the Issues Paper noted that the dose from use of recycled coal ash in concrete block as permitted by EPA can be about 3 percent of natural background (about 10 mrem/yr)), one reason why fly ash is used in concrete is that in 1983 the Environmental Protection Agency (EPA) issued guidelines requiring purchase of cement containing fly ash in both government and private sectors. The guidelines were a response to a directive from Congress to provide some relief to companies that generate fly ash in coal generated electricity with regard to disposal of this high volume, low hazard waste. Indicating at this time that the radioactivity levels in fly ash has set a precedent for another waste product seems egregious. It may be that, if the government had made a greater effort on public participation on this issue originally, the public's sensitivity to unnecessary radiation exposure might have prevented this use of fly ash.

4. Landfill operators

Landfills are run by private companies and an NRC rule in this area could have an impact on siting of new landfills. Comment included:

a) Suggestions for criteria

(A) A standard should be set for unrestricted use below a dose criteria and contain concentration limits similar to those in 10 CFR Part 20;

(B) Criteria should be consistent with international initiatives and State guidelines;

(C) A rule should be consistent with EPA. NRC should adopt EPA risk ranges since EPA seems to have final authority for closure on most sites and 1 mrem/yr should be within what would be acceptable to EPA;

(D) It should have minimal impact on industries susceptible to radioactivity and acceptable to public;

(E) 1 mrem/yr is suggested as a basis for adopting a table of release concentrations for solids and volume limits. A 1 mrem/yr criteria would be sufficiently conservative to protect public health even if all potential exposures are not known;

(F) Case-by-case determinations should be allowed at concentrations higher than in a table for small volumes and restricted uses at 10 mrem/yr.

b) Potential State issues with disposal of radioactivity in landfills

(a) It must always be possible for other levels of government to make independent judgement and decisions regarding more stringent standards. Nothing should be

preemptive of this basic government right;

(b) An important factor to consider is that many States have specific exclusions for all radioactive waste other than naturally occurring radioactive material (NORM). The impact of NRC allowing volumetric contamination in small amounts could cause problems at the facility and with State regulators if material were taken to a disposal facility or a demolition disposal facility. Therefore, release concentrations should be sufficiently low to prevent such problems, e.g., exemptions and general licenses for a number of consumer products;

(c) Municipal solid waste landfills are regulated by federal, State, and local authorities and even if there are any federal requirements, all landfills still have to comply with State and local requirements. Most State agencies and local authorities have banned radioactive wastes from municipal landfills or have more stringent requirements than Subtitle D. Therefore not all municipal landfills will be able to accept cleared material. A full assessment of available permitted capacity must be made. Most landfill projects are highly controversial and adding radioactive waste will generate unfavorable public response which will affect a landfill operators willingness to accept the waste;

(d) Formalization of risk analysis methods for wastes would be beneficial. Disposal of solid materials that have been released for unrestricted use should be acceptable at municipal waste landfills meeting 40 CFR 258, although some States and localities have prohibitions against such disposal. However, if the materials proposed for landfilling have passed the release standard adopted by NRC there should be no reason for objection;

(e) A rule should cover the release of materials for unrestricted release and the release of materials for disposal as industrial landfill (where the risk of exposure to the food chain is low);

(f) There may be overlapping difficulties in responsibilities between NRC, State and local agencies with regard to impacts on landfill management.

c) Cost-benefit considerations

(a) There are two types of impact: (a) real, such as setting off alarms at a landfill, and (b) perceived, which might stigmatize an industry. NRC should avoid or mitigate the real impacts in any proposed rule;

(b) If all the non-contaminated or background level materials from DOE or other sources are removed from the cost-benefit analysis, the remaining volume may be small enough that it can be put in a landfill more cost effectively than recycling it;

(c) Major economic costs and factors associated with landfill disposal of material released for unrestricted use include: (i) replacement costs for LLW disposal sites when existing disposal capacity is exhausted; (ii) storage costs for waste when existing disposal capacity is exhausted and before new capacity is built; (iii) cost of disposal at a low level radioactive landfill (this is extremely expensive relative to other options (e.g., disposal in Subtitle C or D landfill, recycling)); (iv) cost of licensing a facility for disposal, including preparation of an environmental impact statement (EIS); (v) cost of convening and running a commission or committee to analyze alternatives to disposal; (vi) economic impacts of removing land from productive use because it is needed for landfill space; (vii) costs of managing solid waste that sets off detector alarms, and the cost of monitoring and managing landfill leachate that may contain radionuclides.

5. Licensees, including universities, medical facilities, fuel cycle facilities, and nuclear power plants

These groups generally expressed the view that an unrestricted use standard set at a low dose level was acceptable and recommended that NRC adopt the American National Standards Institutes's (ANSI) consensus standard N13.12. Comments included:

a) Health/risk/environmental considerations

(1) The doses and risks being considered are very low and scientific bodies such as the National Council on Radiation Protection and Measurements (NCRP), the International Committee on Radiation Protection (ICRP), and EPA indicate that levels around 1 mrem/yr are negligible or trivial in risk considerations;
(2) Diagnostic medical procedures give patients between 500 to 1000 mrem without adverse effects; therapeutic procedures give a dose of 10,000 mrem or more without adverse effects;
(3) The doses being considered would be insignificant compared to background variations and would be well below doses received in routine activities of life;
(4) EPA allows 4 mrem/yr in drinking water and 10 mrem in air in its standards;
(5) There is an environmental impact of having to replace the material which is thrown away at a LLW site, instead of reusing it in some way.

b) Cost-benefit considerations

(1) There is a benefit that society has realized from productive use of these materials in medicine, in research, in product development, and in power production. Release of low activity materials is part of that cost-balancing equation;
(2) There is a societal benefit in reusing the material;
(3) Disposing of very low activity material with low potential risk in LLW burial grounds is very costly. The cost impact of having to send very low activity waste to LLW can have a severe economic impact on small businesses, universities, and medical facilities and hospitals that handle and use radioactive materials. Health care will be negatively affected by a rule that is unreasonably stringent;
(4) There will be a large negative economic impact on U.S. trade with other countries if the international community establishes criteria and the U.S. does not have a standard or has a much more stringent standard;
(5) The regulatory burden of the current system would be reduced because a simple standard could be established, compliance could be easily verifiable, and there would be fewer requests for approval of alternative criteria for disposal.

c) Public confidence

(1) A standard would increase public confidence because there would be clear safety criteria.

d) Suggestions for criteria

(1) Dose criteria suggested included:
- 1 mrem/yr consistent with NCRP;
- Between 1 and 5 mrem/yr consistent with Appendix I to 10 CFR Part 50, 10 CFR Part 20, and 40 CFR 190;
- 1 mrem/yr and a second level of 10 mrem/yr to allow storage of materials with dose of 10 mrem/yr or less for onsite storage;
- Consistent with EPA drinking water standards and current airborne effluents;

- 10 mrem/yr consistent with statistical variation of background in U.S.;

(2) Site specific criteria should be able to be set based on release scenarios;
(3) Criteria should be set at a level at which the material is defined to be "clean" and should indicate unequivocally that the standard is safe;
(4) Criteria should be based on concentration levels that are reasonable and tied to a dose level;
(5) Criteria should be practical and clear and the theoretical risk should be balanced by observed risk;
(6) Criteria should be based on average member of the critical group and not on a maximally exposed individual;
(7) With regard to the ability to implement a standard:
   - The ability to implement the standard should be considered;
   - Levels should not be set too low or else survey costs could be significant;
   - There is a need for practical criteria that can be used in the field, e.g., need to consider if there are hand held instruments that can measure at these levels;

(8) Criteria should be consistent with international standards.

6. Health Physics Society (HPS) and individuals

This group generally favored a rule containing a criteria for unrestricted use. The HPS provided a position statement which endorsed ANSI N13.12. Commenters noted that ANSI N13.12: (a) contains criteria for release of volumetrically and surficially contaminated materials; (b) is a voluntary consensus standard; the National Technology Transfer and Advancement Act of 1995 requires Federal agencies to use such standards unless their use is inconsistent with applicable law or otherwise impractical; (c) is protective of public health; (d) is consistent with the NCRP and with international scientific organizations which recognize 1 mrem/yr as a negligible individual dose; (e) considers detection capability; (f) contains derived screening levels; and (g) allows for clearance on a case-by-case basis. Comments included:

a) Health/risk considerations

(1) People are exposed to wide variations in background each day from place to place with no discernible effect on health;
(2) Manmade radioactive material should be considered in comparison with natural background, and material should not be considered radioactive it if doesn't contribute significantly to the radiation exposure we already receive from background (levels being considered are only 0.3% of background);
(3) It is illogical to say any amount of radiation is unacceptable because we live in a sea of radiation;
(4) Even if a person receives multiple exposures, they will total only a small fraction of 10 CFR Part 20 limits.

b) Cost-benefit considerations

(1) Trying to achieve a zero risk is a waste of finite financial resources which should not be spent on trivial risks when there are other real risks that need addressing;
(2) Nuclear power stations provide safe clean energy and uses of radioactive material in medicine and research is vital to the U.S. economy and public health, and disposition of the materials used is part of that consideration.

c) Ability to measure/track materials

(1) Values must be detectable and measurable to allow compliance.

7. States and State organizations

Comments regarding suggestions for a standard on unrestricted use included the following:

a) Dose criteria suggested

(1) 1 mrem/yr was suggested and it was noted that specific concentration and activity values must be included to assure consistency among licensees;
(2) 10 mrem/yr to a person receiving a limiting dose would give assurance that 100 mrem/yr will not be exceeded and that a member of general public will get less dose;
(3) There should be provisions for case-by-case evaluation and exceptions for unique cases that vary from the dose limit but provide an equivalent level of protection;
(4) A standard should be in terms of dose for free release of soils.

b) Cost-benefit considerations

(1) The amount of contaminated metal to be recovered is very small compared to overall volume of available clean scrap metal and economic benefits to a few large licensees in salvaging a relatively small amount of material may not be justified in terms of societal or socio-economic costs.

c) Ability to measure/track

(1) A standard should not reference activity-concentration limits. These should be in guidance similar to the license termination rule;
(2) Criteria must be practical to use. It should indicate how MARSSIM would be applied. Licensees' monitoring capabilities will need to be evaluated and upgraded for demonstrating compliance with dose-based criteria in a rule and guidance;
(3) There must be reporting requirements and a strategy to stop release of material if levels exceed limits;
(4) There must be liability insurance for businesses and public if they are affected economically or socially.

F. TECHNICAL APPROACH - RESTRICT USE OF MATERIALS TO ONLY CERTAIN AUTHORIZED USES

In a restricted use approach, material would be restricted to only certain authorized uses This could involve either limiting the material to: (i) some non-licensed use (e.g., bridge supports, public landfills); or (ii) within the nuclear industry (e.g., shipping casks). Comments treated both of these possibilities.

1. Advantages of restricted use

a) Restricting use to only certain non-licensed uses would be acceptable because the material would not end up in consumer uses;
b) This approach may be the only alternative acceptable to the public.

2. Disadvantages of restricted use in unlicensed uses

Some commenters, including those in the metals industry, States, and the licensed nuclear industry, indicated that restrictions to non-licensed uses may not be practical or may not be

effective in ensuring the materials remain in their restricted use. Comments included:

a) It would be difficult to enforce and it is not clear that institutional controls would work to limit where the material goes;
b) This approach may not be economically viable (e.g. bridge girders) because the limited quantities involved from licensed facilities would not be sufficient for a mill to run economically;
c) It would involve a complicated process and burden on NRC and the nuclear industry;
d) There could be additional burden on State and local regulatory authorities and the waste disposal community. There would be a need for a system of tracing and accountability that would create a new class of license that would have to be inspected. There could also be issues that arise when such materials cross State lines;
e) Market forces should determine if restricted use is practical;
f) Unlike some other countries (France did establish restrictions on use), in the U.S. the destination of material cannot be stipulated unless it is designated as a form of hazardous or radioactive waste.

Some commenters noted that, even with restrictions on use, NRC would still need to define an unrestricted use criteria for when the authorized use ended because restricted use is really a delayed release of solid materials for unrestricted use and the material will eventually be released after the restrictions end. Comments included:

a) NRC should just pursue a solution for an unrestricted use criteria. It is premature and too difficult to try to also pursue a restricted use approach at the same time;
b) Setting an unrestricted use standard would provide a more universal standard with regard to applicability;
c) Points in the process would need to be defined to indicate where authorized use would begin and licensed control would end.

3. Suggestions regarding approaches for restricted use

a) Material should be kept under licensed use or within the DOE (e.g., waste containers, shielding blocks, etc). It was suggested that such a scheme can already exist under NRC's regulations and it is not necessary for NRC to do a rulemaking. However, a comment noted that there is too much material potentially available for release for it all to be used as shield blocks at DOE facilities;
b) A dedicated facility could be used to melt and handle these materials as a licensed NRC facility. Metals would be refined and melted and also cleaned up by a regulated facility. In this type of scenario, the dedicated melter products could be regulated;
c) A restriction requiring disposal in a solid waste landfill could be considered. This would allow doses to be estimated and LLW site capacity to be preserved. This could include a standard for release of materials in various types of landfills. It was also noted that material should not be restricted to landfill disposal unless there is a health and safety basis for not permitting unrestricted use. NRC and licensees can work with States regarding this alternative once NRC has established safe levels for release of materials destined for disposal at landfills;
d) Solid material with very low amounts of radioactivity could be sent to an intermediate disposal facility, such as the Envirocare disposal facility in Utah;
e) In setting restrictions, there is a need to consider such aspects as the type of material, and the type and nature of authorized uses;
f) If materials are restricted to a solid waste landfill, advantages include:
   (1) The dose pathway would be easier to evaluate for landfill disposal than recycle;
   (2) Release to municipal landfills would limit public exposure, further protect public

health and safety, and preserve existing LLW disposal capacity;

(3) Other uses of materials appear to burdensome from a compliance and enforcement standpoint.

g) Potential problems associated with restricting materials to landfill disposal include: (i) local constraints such as State law or land use permits conflicting with landfill disposal; (ii) not all industrial solid waste facilities meet the 40 CFR 258 standards; use of the term sanitary waste landfill is misleading because it implies domestic sewage; (iii) segregation of released material from natural material is difficult when material goes to a landfill; (iv) contaminated concrete may get recycled for use in aggregate by a landfill; and (v) a waste acceptance method and risk assessment method should be formalized for both unrestricted use and release for disposal; and (vi) minimizing the volume of low-level waste should be an overriding consideration; .

G. TECHNICAL APPROACH - PROHIBITION ON RELEASE OF MATERIAL FROM RADIOACTIVE AREAS

As noted in Section B of this attachment, a prohibition approach would involve not permitting release of solid material that has been in an area where radioactive material has been used or stored, and instead require all such materials to go to a LLW disposal facility. Comments on this approach included:

1. Advantages of a prohibition on releases and other issues

a) In general, comments supporting prohibition also cited the reasons for opposing unrestricted use listed in Section E.2 of this attachment;
b) Only prohibition is reasonable and protective. No additional exposures are acceptable;
c) Material should not be allowed in landfills, incinerators, etc;
d) The prohibition alternative has not been fairly addressed in the issues paper;
e) Prohibition of releases would represent a cost savings for NRC because dose calculations for case-by-case releases would not have to be done;
f) In addition to prohibiting further releases, there should also be a full reporting on, identification of, and recapture of any material released so far.

2. Disadvantages of a prohibition on releases and other concerns

a) Sending very low contaminated materials to LLW would have negative impacts of causing the incurring of very high costs to dispose of this material in LLW, harming society by significantly increasing cost of goods and services provided by use of nuclear technologies, and depleting limited LLW space unnecessarily without a commensurate increase in protection of public health;
b) It would be wasteful of valuable resources;
c) Biomedical research could be curtailed or stopped if all materials (e.g., boxes for equipment unpacked within controlled areas) have to go to LLW;;
d) It ignores reality that radiation is a fundamental part of the world we live in. The radiation levels in air, water, food, earth and background vary widely in space and time and completely overshadow annual exposures being considered here;
e) Any prohibition must consider excluding items that have no history of exposure to licensed radiological operations because these should be of no concern to NRC, e.g., fences around sites;
f) NRC would need to consider what is the boundary between things that could be released and those that would go to LLW; e.g., would the entire restricted area to be affected, including administrative offices, etc;

g) A standard in European countries of, for example 10 uSv/a (1mrem/yr), would mean that U.S. authorities need to consider what would happen to material imported to the U.S. under an NRC standard which prohibited release, i.e., would NRC have to license such material imported in the U.S.;
h) Total prohibition could be impractical because more mobile materials might be included along with fixed, discrete items.

H. OTHER TECHNICAL APPROACHES SUGGESTED

The issues paper indicated that other approaches besides those listed in the Issues Paper would also be considered. Comments on other approaches for control of solid materials included:

1. Different standards could be established for reuse and disposal due to inherent differences between reuse of materials and disposal in landfills;
2. Different standards could be based on the fact that material at nuclear facilities is separated based on whether it came from restricted areas or unaffected areas;
3. There is a range of material at nuclear power plants that includes institutional trash, asphalt, concrete, roofing and scrap metals, and materials available for re-use (e.g., trucks, scaffolding, computers) that could be treated differently;
4. Some material could be cleared but other material, like potentially recyclable steel, would not be released or could be restricted as to its use;
5. Use of a pilot program for control of different materials might be appropriate.

I. ISSUES WITH DEVELOPMENT OF NRC'S TECHNICAL BASES

There were a number of comments raised on NRC's development of a technical basis to support decision-making. The technical basis development is discussed in Attachment 3 of this paper. Comments included:

1. Issues with conflict of interest (COI) of contractor

a) With regard to NRC's technical reports, the contractor performing technical basis analysis for the NRC has a COI. NRC's rulemaking effort is, and will continue to be, compromised by this COI if this contractor is not removed from this effort;
b) Draft NUREG-1640, which was prepared by the NRC contractor with the COI, should be withdrawn;
c) NRC should have an independent analyses of its reports and consider using an independent consultant to conduct technical analyses that everybody would be satisfied with;
d) SAIC had a contract with NRC to do an issues paper and analysis of comments which was not appropriate because the NRC should be doing that work.

2. Analyses supporting decision-making should consider the following:

a) Analyses related to dose assessment and/or environmental analysis should consider

(1) Exposure to multiple sources and effect of multiple products made from released material. It was noted that metal recyclers generally receive materials from multiple locations. Some comment indicated that detailed analysis of multiple sources is not necessary because of conservatism build into the calculations and the potential dose standard being significantly less than 10 CFR Part 20 limits for the public;
(2) Total impacts of all doses, all products, and all future uses to all members of the public, on the gene pool, on other species, on workers and their progeny. The analyses needed here would require many unverifiable assumptions and call into question the ability to do a full analysis, especially when inventory is uncertain and computer models may not be sufficiently accurate;
(3) All nuclides, all materials, all pathways, extra burden on immune systems, and interrelationships and compounding of effects with other toxins in the environment;
(4) Cumulative impact of potential build-up of radioactivity in materials and the environment over many years. Some comment indicated that an analysis of buildup can be fairly straightforward;
(5) Whether levels are safe and what are the chronic and acute risks;
(6) Specific impacts for sensitive populations;
(7) Differences of opinions were expressed on whether analysis should use a reasonably maximally exposed individual or an average member of the critical group;
(8) The large quantities of material at DOE facilities (or else a rulemaking should not proceed);
(9) Disposal scenarios as well as recycle/reuse scenarios, including the compete range of materials routinely released. Analysis used for disposal at a landfill could be simplified;
(10) Assumptions should be realistic and not excessively conservative but provide for public health and safety;
(11) Environmental impacts and societal impacts and balance protection of human health and the environment;
(12) The many ways that concrete is used should be considered and potential radiation exposures as a result of radioactive material in concrete should be based on a scenario that the public would be constantly exposed to the concrete during their entire lives.

b) Analyses related to cost-benefit should consider

(1) The overall benefit to society of licensees that use radionuclides, such as utilities (which produce power), medical facilities, companies that make smoke detectors, etc.;
(2) It may be appropriate to weight some technologies higher than others (e.g., medical uses might be higher);
(3) The value assigned to contaminated steel. For example, if portal monitors at a steel facility alarm, then the steel will have no value (or it may even have a negative value). Any analysis should also look at the cost of abandoned material;
(4) The costs and impact on consumers of sending material to LLW or to controlled release which will depend on the level that is set in any standard;
(5) Costs for changing survey equipment and protocols to meet any new standard;
(6) Whether there is recycle value of metal from nuclear power stations;
(7) Potential negative impacts on non-nuclear commerce, e.g., film industry, electronics. Some comment indicated that the range of impacts is small and can be readily evaluated;
(8) Any additional analysis and review may not be productive, and rulemaking should not proceed, unless NRC first addresses the public perception of associated risks and the

effect on the affected industries' markets;
(9) Examination of the provisions for liability that would exist if a release exceeds the dose limits;
(10) The benefits in reduction in costs for disposal at landfill vs. LLW;
(11) Costs of implementation and ability to measure;
(12) Costs associated with disposal alternatives, onsite storage, etc.;
(13) The benefits that would accrue to all parties including States and public;
(14) The mass of slag vs. mass of scrap, uncertainties in nuclide concentration in recovered metal and nuclide concentrations in scrap and in risk estimates and uncertainties in slag uses and localized contributions to exposure pathways that could underestimate doses;
(15) Regional background count parameters in model variations;
(16) The possible loss of market and economic injury to the industries receiving the licensees wastes.

J. OTHER PROCEDURAL COMMENTS

Other comments were also received on various procedural issues regarding the establishment of criteria for control of solid materials. Comments included:

1. Need for stakeholder involvement

a) Stakeholders should be allowed to agree upon facts and parameters and acceptable methods of dealing with materials and NRC should implement such a finding;
b) NRC should form an advisory task force of stakeholders which would report to the NRC on criteria for acceptable release and recycle based on clarification of critical issues, review of all factors, dialogue between stakeholders towards achieving consensus;
c) In evaluating any alternative, the right of the individual to decide and choose, or not choose, the risk of exposure should be considered;
d) The public has spoken in opposition before on the below regulatory concern (BRC) policy and on other previous efforts in the late 1970's and early 1980's. This resulted in passage of the Energy Policy Act in 1992 revoking BRC. NRC should not try again with this similar effort which will have the same result;
e) NRC ignored public comment and did not adopt their recommendations on the decommissioning rulemaking in the early 1990s;
f) NRC should not make decisions on unfounded fear;
g) Public perception concerns can be treated by following an open public process that addresses public concerns as they are identified and by developing a safe practical standard and by defending the standard as fully protective;
h) NRC must state clearly that its standard is safe so as to not undermine public confidence and possibly do economic harm to licensees;
i) The rights of State and local governments to impose stricter standards and any possible limitations thereon under the interstate commerce clause should be considered.

2. The process has a predetermined outcome

a) This process has a predetermined outcome and is therefore illegitimate and flawed. The government is doing what industry wants for their economic benefit; and NRC won't seriously consider the option of isolating radioactive wastes. Both options in the Issues Paper (no rule and rule) pre-suppose that some releases, either detection-based or dose-based, will take place;
b) Because this process is predetermined, the environmental community boycotted the Fall 1999 public meetings rather than legitimize the process;

c) The process is predetermined because the June 30, 1998, Staff Requirements Memorandum (SRM) directs the NRC staff to promulgate a dose-based rule for clearance of material.

3. Need more study before a decision can be made

a) Until more analyses of technical information base and more extensive research and study of effects, etc, are complete, NRC should put this process on hold and suspend releases unless there are ironclad assurances that the plan is totally safe. Otherwise, many situations have been proven to be dangerous after they were allowed or after long term exposure;
b) The timing of the reports on soil analyses and technical support for a National Environmental Policy Act (NEPA) and cost-benefit analyses is very important;
c) There were some comments that the comment period should be extended whereas there were other comments that it should not be extended.

4. State/Federal issues

a) States should have flexibility in application so that case-by-case evaluation may still be performed by a State;
b) A rule must be compatible with State requirements;
c) States must be involved and NRC must work with DOE, EPA, the Department of Defense (DOD), and the Department of State (DOS), to establish a uniform system of standards, to harmonize method of calculations and dose/risk standards, and to get public confidence;
d) Business and industry representatives and State regulated landfill operators must be involved;
e) DOE facilities should be included within the scope of an NRC rulemaking because an NRC rulemaking will affect DOE facilities as DOE will likely try to be consistent with whatever NRC proposes and DOE possesses a large amount of waste material;
f) EPA needs to step in to deal with this; this is EPA's responsibility and NRC should not do this effort.

5. Other

a) NRC should set health-based standards and allow the market to work within the bounds of the standard;
b) There would be a class action suit against NRC if it goes ahead with this plan;
c) Sixteen States have passed laws and regulations more restrictive than NRC's mostly with intent to continue regulatory control if NRC deregulates.

K. COMMENTS RELATED TO INTERNATIONAL ISSUES

Comment was received on the relationship of this effort to international initiatives being considered (See Attachment 4 of this paper). Comments were divided on how to factor international initiatives into NRC decision-making. Comments included:

1. NRC standard should be consistent with the international initiatives

a) International implications of setting a standard should be considered and NRC's effort should be consistent with international initiatives so as to avoid developing a NRC standard that may have adverse impacts on international trade;

b) The trade impacts associated with inconsistent standards could be very costly;
c) Other countries do not have the capability to replace metals as easily as the U.S. and need to develop standards in this area; the U.S. imports material derived from recycled radioactive material.

2. NRC should not be bound by international efforts

a) With regard to international standards setting, NRC should take a leadership role in what a standard should be. Some comment noted that this should involve taking a lead with regard to the approach suggested by the metals industry (See Section E.1 of this attachment) and other comment suggested this should involve an approach of not permitting release;
b) NRC should not follow international standards that are set if they permit releases;
c) Regardless of what other countries may do, the Customs Service should reject any shipment of metal that sets off a sensor set at background. Comment suggested that this is needed due to the incidents of illicit tracking of radioactive sources across borders and illegal trade and is needed to better safeguard our borders.

L. COMMENTS ON ADDITIONAL MATERIALS AS CANDIDATES FOR RULEMAKING

With regard to types of materials that should be covered in a rulemaking, it was noted that:

1. Various materials that go in and out of nuclear facilities on a daily basis should be addressed in rulemaking (besides ferrous metals, aluminum, copper and concrete that were considered in NUREG-1640), e.g., patient waste, soiled, sewage, sludge, lead, titanium, nickel, NORM, mixed waste, etc;
2. A suggestion was to do a dose standard that would be applicable in general and specific materials could be addressed in guidance;
3. Materials at DOE facilities should be considered, including classified materials and nickel, because DOE has a large volume of material (much larger than that at licensed facilities), and because DOE has noted that it would likely be consistent with NRC in its criteria;
4. It was suggested that if issues on disposition of steel impede progress in setting a standard, consideration of steel could be set aside until an international standard is developed and that those materials that are most common candidates for release, reuse, or direct disposal should be considered first. However there should not be a blanket prohibition of metal recycling since there is no definitive health and safety basis for such action. Initially release of non-reusable materials could be addressed (e.g., concrete, construction materials, clothing, trash) for disposal in landfills;
5. Additional non-metals to consider include: activation products, aerosol and spray paint cans, asphalt, batteries, boroscopes, boxes, drums, containers, building materials, chains, ropes, hoses, and tubing, charcoal oil, chemistry reagents, clothing, including gloves and shoes, complex mixtures of materials, consumables, demolition wastes, (particularly hydrogen fluoride from 700,000 tons of DOE UF6), dried solids (e.g., collected from oil interceptors and holding ponds), dry resin, extension cords, fluorine, fire extinguishers, fly ash, furniture, grease dunnage, industrial wastes, institutional trash, mixed waste,non-metals in general, nylon slings, paints and solvents, patient waste, research materials and laboratory wastes, roof gravel, sanitary wastes and associated equipment (e.g., plumbing snakes), secondary resins, slag, slightly contaminated fuels, sludge, sewage, welders and welding rods, and wood.
6. Materials that specifically should not be released include plutonium, transuranics, other radioactive isotopes that do not naturally occur in nature, and materials that would create large numbers of exposed individuals.

ATTACHMENT 3

STATUS OF TECHNICAL BASIS DEVELOPMENT

A. PURPOSE

The purpose of this attachment is to inform the Commission of the status of the technical basis work that is being performed by the staff and its contractors. This attachment discusses work that could be developed to support a rule or to update existing guidance.

B. INTRODUCTION

During the past several years, the staff has developed methods for assessment of doses to individuals as part of a technical basis for clearance of materials from nuclear facilities. This effort resulted in the establishment of material flow models and potential exposure scenarios for copper, aluminum, steel, and concrete. The dose assessment methodology was developed in consultation with other Federal agencies, namely, the EPA and DOE, as well as the IAEA. This effort culminated with the publication in March 1999, of a draft report entitled "Radiological Assessments for Clearance of Equipment and Materials From Nuclear Facilities" (NUREG-1640). The methods and results contained in the draft report may be used for translation of a hypothetical individual's dose from concentrations of radioactivity in or on metal and concrete.

In early 1999, the staff identified several areas that required additional technical assistance to support decision-making on the clearance of solid materials, including holding public meetings. NMSS and RES coordinated the award and management of six contracts to: (1) support public workshops (Meridian); (2) perform technical work on dose assessment and costs (Science Application International Corporation); (3) evaluate environmental impacts and cost-benefit analyses (ICF Consultants, Inc.); (4) search the literature for soils uses (U.S. Department of Agriculture); and (5) extend survey methods and estimates of survey costs for clearance(Oak Ridge Institute for Science and Education and the DOE's Environmental Measurements Laboratory).

Complicating the technical basis development have been issues, raised in public comment, associated with a conflict of interest (COI) with one of the contractors, SAIC. On March 17, 2000, the staff entered into a no-cost termination settlement agreement and terminated the SAIC contract NRC-04-99-046. As part of the settlement agreement, SAIC agreed not to seek reimbursement of invoiced costs in the amount of $120,000. The staff is evaluating alternate plans for proceeding to develop technical bases. Certain technical basis development work will be more impacted by the contract termination than others, as described in the following sections.

Descriptions of the technical basis work are divided into five interrelated sections, each with the following format: (1) a description of approach for technical assistance; (2) work to date; and (3) future work plans.

C. INDIVIDUAL DOSE ASSESSMENTS (DRAFT NUREG-1640)

1. Approach for Technical Basis Development

In order to establish criteria for clearance of materials, it is necessary to estimate what hypothetical dose an individual might receive from residual radioactivity in solids. Draft NUREG-1640 describes the scenarios, models, calculation methods, and results of such analyses for individuals over a broad range of scenarios. The scenarios were designed to cover the probable fates of iron and steel, copper, aluminum, concrete and equipment for reuse if cleared to enter the general stream of U.S. commerce from a nuclear facility. These scenarios were also designed to identify the critical group, which is the group of individuals reasonably likely to receive the highest dose.

2. Work to Date

A substantial portion of the technical basis for this analysis was completed with the publication of the December 1998 draft, "Recycle/Reuse Literature Search Report," and draft NUREG-1640. The latter document was issued for public comment in March 1999 and the public comment period closed in December 1999. Currently, comments are being evaluated by the staff.

3. Future Work Plans

In response to the comments, draft NUREG-1640 needs to be revised and completed. However, during public comment period, issues were raised concerning a COI with the contractor, SAIC, that provided technical assistance on the draft NUREG-1640. In response, the staff obtained additional information on this matter and, based on its review, on March 17, 2000, the staff entered into a no-cost termination settlement agreement and terminated the SAIC contract. Currently, the staff is evaluating alternate plans for proceeding to develop technical bases.

Completion of draft NUREG-1640 may not be necessary for NRC technical basis development, but would be useful as a tool for estimating doses associated with surficial and volumetric clearance criteria that may be developed by other Federal, State, or international organizations.

D. ADDITIONAL DOSE AND COST ANALYSES

1. Approach for Technical Basis Development

As described in Section A of this attachment, the technical analyses developed to date is limited to *individual* doses only. If an alternative involving rulemaking were to be pursued, a draft Generic Environmental Impact Statement (GEIS) and draft Regulatory Impact Analysis (RIA) would need to be prepared in support of decision-making on technical approaches, as discussed in Section G of this Attachment. *Collective* dose and cost impact estimates are required for the development of these documents. Because collective doses for copper, aluminum, steel, and concrete, which are the materials analyzed in draft NUREG-1640, have not been estimated yet, additional technical basis development on doses and costs is necessary. In addition to the scenarios already established in draft NUREG-1640, there may be potential population doses from additional scenarios that need to be examined.

Further, the amounts of materials and equipment and the kinds and amounts of radioactivity associated with scrap metal needs to be established in relationship to the potential regulatory alternatives for clearance. This information is required to calculate collective doses and to estimate the cost-benefit of regulatory alternatives. In addition, the Commission requested that the technical basis be comprehensively applicable to all materials; therefore, the assessment for clearance of other materials may be required. Soil is one of the materials the staff is

assessing, based on direction from the Commission, which is described further in Section E of this Attachment.

Technical basis development would be needed in the following areas: (1) an assessment of the inventory of materials that would likely be available for release from various national and international sources; (2) an assessment of collective doses; and (3) an assessment of costs associated with clearance of materials using the attributes needed to support a regulatory analysis. Additional information on these areas is provided below:

(a) Inventory. This work would estimate the types and amounts of scrap metal and equipment that are candidates for clearance, along with their radiological characteristics, and the potential for build-up of radioactivity in materials. Assessments of both the potential collective dose and the potential costs and benefits of a clearance rule depend on this information. Information is also needed on the value of scrap or the costs for its disposal, which depends on its form, quality, and quantity.

Additional inventory information is needed to establish baseline levels of nuclides in materials; the projected contribution of changing international trade and domestic trade practices to changing baseline levels; clearance of materials from NRC licensees and Federal facilities; entry into general commerce of radioactively contaminated materials from other domestic sources (e.g., oil and gas industries), and adoption of international clearance levels.

(b) Dose Assessment. As noted above, currently NRC only has detailed information for individual dose assessments and analyses in a draft GEIS and RIA must treat collective doses in considering environmental impacts and cost-benefit.

In addition to collective doses to groups of people, the potential for exposures of one individual to multiple materials, as well as multiple exposures to the same cleared material, needs to be considered. Additional materials to be analyzed beyond the materials in NUREG-1640 would include various rubbles or sediments such as gravel, asphalt paving, roofing materials, sludges, resins, and sediments.

(c) Costs. Costs analyses require a detailed characterization of the materials inventory that is potentially available for clearance. Costs of collective dose, transportation, disposal, and non-radiological risks would be estimated along with the benefits, such as cost avoidance. The costs would be estimated incrementally in accordance with the regulatory alternatives chosen for the cost-benefit analysis, which is discussed further in Section G of this attachment.

2. Work to Date

SAIC had been contracted to develop this technical basis. The plan was to begin work on inventory of steel, copper, aluminum and concrete, followed by work on collective doses from these materials and draft NUREG-1640 scenarios, and then cost estimates for these materials and scenarios. The results of this work were to be provided to other contractors working on other aspects of the technical basis. Subsequent work on additional materials and scenarios was planned upon completion of the aforementioned tasks. Also, it may be useful to develop dose assessment methods and cost evaluations similar to those described above, as a tool in specific licensing reviews or in regulatory interactions with other Federal, State, or international organizations on clearance.

However, during public comment period, issues were raised concerning a COI with SAIC. In response, the staff obtained additional information on this matter and, based on its review, on

March 17, 2000, the staff entered into a no-cost termination settlement agreement and terminated the SAIC contract.

3. Future Work Plans

The original schedule was to complete the technical basis development by August 2001. However, this schedule is no longer valid due to termination of the SAIC contract. Currently, the staff is evaluating alternate plans for proceeding to develop technical bases.

E. SOIL TECHNICAL BASIS DEVELOPMENT

1. Approach for Technical Basis Development

In a SRM dated June 30, 1998, the Commission directed the staff to include soil in its overall technical basis development. In response to the SRM, the staff sent the Commission a paper (SECY-99-028) which stated that, both from its experience and from information received from licensee groups, it is important that soil is included in the technical basis development. However, soil was not one of the materials included in the draft NUREG-1640 analyses. Although draft NUREG-1640 does not include soil, work done previously for the license termination rule in draft NUREG-1496,"Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," 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 which can be adapted for use in documents prepared to assist in decision-making.

Development of a technical basis for estimating hypothetical doses which could result from residual radioactivity in a soil matrix requires the establishment of individual and collective dose factors for use in a draft GEIS, RIA, and Regulatory Guide, if a rulemaking alternative were to be pursued. The work planned for developing these dose factors includes establishing scenarios and exposure pathways to the average member of the critical group. The same range of radionuclides analyzed in NUREG-1640 would be used for soils. In addition, staff plans to evaluate the differences, including their rationale, between the draft NUREG-1640 and license termination rule technical bases. Thus, the work conducted on soils is planned to be developed in a collaborative effort with other portions of the overall technical basis.

2. Work to Date

In May 1999, the staff began obtaining data on the use of soils in the United States so that exposure pathway modeling will reflect realistic exposure scenarios to radiologically contaminated soils. These soils could be excavated and transported offsite for use in commerce or by the general public once the soils were released from NRC-licensed facilities. The staff began its own literature search to obtain a reasonably complete characterization of such relevant soil usage. However, during the course of the staff's literature search, it became evident that additional technical assistance was needed from professional soil researchers to acquire the specific information needed by the staff.

In August 1999, the staff contracted with the U.S. Department of Agriculture's National Agricultural Library staff to conduct a comprehensive literature search on relevant soil-usage scenarios. The goal of this effort is to develop a database and the supporting references to provide NRC staff with current information on potential soil exposure scenarios and parameter

values for dose assessment. Since soil as a commodity is not well characterized in the literature, a literature survey was undertaken of more than 500 databases covering science, technology, business, news and other categories, and the internet. From the more than two million records that were initially found in the databases searched, subsequent targeted search strategies recovered 77,877 titles for review. The staff screened these titles and selected a final listing of documents for review.

The results of this effort were documented in a letter report that was sent to the NRC Public Document Room on December 8, 1999. As a result of this effort, the staff has prepared a draft NUREG, "Human Interaction with Reused Soil: A Literature Survey." The report also describes the procedures and results of the extensive literature search. It will be issued in draft form to solicit public comments on the literature search findings and to actively seek additional documented information sources for developing soil reuse scenarios for use in dose assessments related to residual radioactivity.

3. Future Work Plans

The draft NUREG would provide an important part of the technical basis development on soils. It lists about 70 references the staff will further evaluate for the purpose of developing exposure scenarios for the reuse of soils. The staff plans to review the references and extract useful information to establish the scenarios and estimate relevant parameters involved in soil reuse (e.g., contact time, soil type, number of people involved, volumes of soils, etc.) to supplement reviews already undertaken. To facilitate this task, a table has been developed to organize information regarding how soil may be reused and how people may come into contact with it. Column headings refer to potential soil reuse scenarios, rows list information important to describing parameters important for modeling exposure. Public comments are specifically requested to provide data that would complete and/or expand the soil reuse scenario framework.

Once a scenario is identified, more detailed information on human activities and behavior is needed to define the important exposure pathways. It should be noted that a complete scenario may have more than one set of exposure pathways, depending on the expected activities of the exposed individuals. As an example, for gardening activities within the suburban scenario, exposure pathways could include inhalation, ingestion of vegetables or fruits, inadvertent ingestion of soil, and external exposure. To evaluate the potential overall impact of soil reuse, several scenarios would need to be analyzed to determine the critical group. The critical group is the group of individuals reasonably expected to receive the greatest dose from residual radioactivity for any applicable set of circumstances. The dose to the average member of the critical group is then calculated.

Upon completion of the development of supporting information on scenarios, exposure pathways, and critical groups, the staff plans to document its findings in a separate draft NUREG and publish it for public comment. The draft NUREG would also address analyses used by other Federal agencies in regulating soil or soil-like material, such as the EPA's approach to regulating coal ash. Following the review of public comments on the soil exposure scenarios, exposure pathways, critical groups, and dose factors, the staff plans to complete its analysis and prepare a final NUREG incorporating public comments, which would complete the development of individual dose factors for soil.

The next step in the technical basis development on soil would be the assessment of collective dose and costs. Although the staff would be collecting supporting information during the development of the other NUREGs related to the soil technical basis, the analyses required

under this portion will likely be more complex because of the diverse uses of soil in commerce in different locations throughout the United States.

It may be useful to develop soils information for use in other areas, such as the evaluation of 10 CFR 20.2002 disposals, during decommissioning, and for use as an aid in regulatory interactions with other Federal, State, or international organizations on clearance.

F. SURVEY ANALYSES

1. Approach for Technical Basis Development

Measurement and analysis of residual radioactivity at or near background concentrations, either on the surface or when radioactivity is contained within the materials itself, has been a technical challenge. Previously, staff developed technical information in this area to support the license termination rule, which was issued in July 1997, and development of the draft Regulatory Guide for the license termination rule. The supporting technical basis was contained in NUREG-1505, "Nonparametrical Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys," NUREG-1506, "Measurement Methods for Radiological Surveys in Support of New Decommissioning Criteria," NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions," and NUREG-1575, "Multiagency Radiation Survey and Site Investigation Manual" (MARSSIM).

Although these documents provide baseline technical information on survey methods for lands and structures with residual *surface* radioactivity, they do not include survey methods that are applicable to materials and equipment with low levels of residual radioactivity on their surfaces and distributed throughout a volume. Therefore, these documents need to be updated to support the development of a draft Regulatory Guide. It is essential that work conducted on the draft Regulatory Guide be developed in a collaborative effort with other portions of the technical basis.

As discussed previously in this attachment, the staff is evaluating technical information, including environmental impacts and the cost-benefit of alternatives. As part of the cost-benefit analysis, the staff is developing costs for conducting surveys at various dose levels and evaluating the corresponding regulatory guidance to provide licensees with information on how to demonstrate compliance with radiological criteria. Guidance would be provided on, for example, measurement methods for low concentrations of volumetrically contaminated materials that exist in various equipment and materials types, shapes, and sizes that are anticipated to be available for release. The analyses would include the cost of measurement and would also be used to evaluate the practicality of measurement options available to licensees. The primary approach the staff is taking involves the application of nuclide-specific measurements for increased detection sensitivity as well as alternative statistical methods.

Currently, staff is working with two different contractors to develop a technical basis on survey methods. ORISE is the lead NRC contractor supporting the NRC staff in developing survey cost estimates and technical support on survey methods using "off-the-shelf" instrumentation. ORISE and the EML would assist the staff in evaluating implementation issues, developing subsurface analysis methods for both soil and clearance materials, and expanding the statistical tests for subsurface measurements.

The technical approach for developing survey method information may entail the application of more sophisticated survey instruments than are currently used in practice. Continuing

development of new statistical methodologies to plan, conduct and interpret the results of the survey is also necessary. The statistical methodology must also be coupled to the measurement technique to account for effects of certain factors, such as instrument response, the radionuclide chemical and physical form, the size and complexity of the material, and the residual radioactivity level relative to the background radiation level to assure that the appropriate criteria have been met. The contractors would assist the staff in addressing these challenging technical issues.

2. Work to Date

The staff and its contractors are conducting literature searches on the state-of-the art in surveying to take into account advances in instrumentation and measurement methods. However, some of the information on developing measurement and analytical techniques are proprietary to commercial companies and, in some cases, related to nuclear non-proliferation activities. The staff is currently working with vendors and radiation detection and measurement experts to obtain comprehensive information on the commercial availability of such instrumentation.

ORISE and EML began work on this portion of the technical basis in August 1999. The staff has expanded research on the simplification of survey methodologies of surface measurements to include subsurface contamination, which is a contamination configuration that is expected in materials potentially available for clearance. This research is expected to reduce or optimize the effort required to provide statistically meaningful results using a minimum number of samples. This work is applicable to all solid materials that require sampling below the visible surface or any other radiation survey that requires collecting radiological knowledge below a surface.

To date, the contractors have provided information on the following: (1) identification of facilities for survey estimates; (2) radionuclides of concern at the facilities; (3) preliminary information on the scope of survey effort at one facility; and (4) preliminary results of a literature review on survey instrumentation. There will be schedule impacts due to the termination of the contract with SAIC (see Section D of this attachment).

3. Future Work Plans

Independent of whether a rulemaking alternative is pursued, this work could be used by the NRC staff and by other Federal agencies to resolve existing and potential inconsistencies in the approaches and procedures for measuring low levels of radioactivity in or on contaminated equipment and material. In support of developing implementation guidance for the rulemaking on radiological criteria for licence termination (Subpart E of 10 CFR Part 20), the staff worked with other federal agencies to develop the MARSSIM (NUREG-1575). MARSSIM was developed to deal with the concerns and problems associated with making radiological measurements at low levels, but was limited to *surface* contamination in buildings and land areas. Although MARSSIM has been adopted nationally and is being used internationally for survey guidance, a limitation of MARSSIM is that it does not address subsurface contamination measurements and volumetric contamination in soils, materials and equipment. The staff considers MARSSIM the appropriate document to establish consist federal guidance for the control of solid materials.

The NRC staff participated fully in the development of MARSSIM and contributed significantly to its technical basis by developing the supporting analyses in NUREG-1505, NUREG-1506, and NUREG-1507. Currently, similar supporting documents for the clearance of solid materials are not available for incorporation into MARSSIM. Additional time and effort will be needed to expand or append MARSSIM and its technical basis to include subsurface measurement

guidance. However, a draft Regulatory Guide developed independent of MARSSIM could be developed by the staff and its contractors separately, which may expedite completion of the guidance.

Plans for future work by the staff and its contractors include survey cost estimates and the development of a technical approach for conducting surveys. The staff expects to obtain general information on instrumentation and measurement and more specific information on difficult geometry sampling and analysis using advanced methods and a final report on survey methods. Regarding the development of survey costs, the staff expects estimates for various facilities and measurement methods using "off-the-shelf" instrumentation and plans to develop additional estimates using advanced survey techniques once they have been studied further.

G. TECHNICAL EVALUATION FOR REGULATORY ANALYSIS

1. Approach to Technical Basis Development

The staff is working with a contractor, ICF Consulting Inc. (ICF), to document public comments on the Issues Paper, which is discussed in greater detail in Attachment 2. Should the rulemaking alternative be pursued, the staff and its contractor would prepare regulatory analyses of options consistent with NEPA and Executive Order 15992. A draft GEIS and RIA would be prepared to address the affected environment, environmental consequences, radiological and non-radiological risks, socioeconomic factors, such as environmental justice and expected land use, and the cost and industry impacts associated with implementation of diverse radiological criteria for clearance. If another alternative is pursued, such as updating guidance, work of this nature to support value-impact assessment for the guidance would still be needed.

Development of a GEIS and RIA are dependent on products from other staff and contractor analyses, such as those discussed in previous sections of this attachment. In particular, information on inventory, dose assessment and costs are essential to calculate collective doses and estimate the cost impacts of regulatory alternatives. Additional analyses for individual and collective doses may be needed to cover other materials, such as soil, and implementation consideration, which have not been analyzed yet.

2. Work to Date

As discussed in Attachment 2 of this paper, the staff held a series of workshops on the Issues Paper in fall 1999. During the workshops, the staff began the early stages of scoping under NEPA by discussing the regulatory approach for conducting the required analyses and, with assistance from its contractor, summarized public comments on different options for the control of solid materials. A database was utilized to prepare the summary of public comments contained in Attachment 2 of this paper.

A standard format and guidance document was prepared that could be used by the staff and its contractors to more efficiently prepare and analyze cost-benefit data, should a rulemaking be pursued. In addition, the feasibility of materials and inventory acquisition for NRC-licensed and non-NRC licensed generators has also been evaluated.

3. Future Work Plans

As discussed in Sections B, C, and D of this attachment, complicating this effort is the termination of the SAIC contract for development of the technical bases. The results of the SAIC contract were to provide input to the ICF work on the GEIS and RIA. However, the SAIC

contract was terminated on March 17, 2000 and currently the staff is evaluating alternate plans for proceeding to develop technical bases. The staff will be considering the effect of that evaluation on this effort.

If a rulemaking alternative is pursued, an assessment of rulemaking alternatives would be made. This would be followed a preliminary draft GEIS and RIA, and a revised draft GEIS and RIA, and public interaction in development of the documents. The staff would then prepare an FRN proposing a rule, a draft Statement of Consideration, and supporting documentation. This would entail the analysis of and response to public comments related to the scoping process.

ATTACHMENT 4

INTERNATIONAL ASPECTS OF CLEARANCE

A. PURPOSE

Provide information to the Commission on: the status of clearance regulatory efforts internationally; relationships of an NRC clearance rulemaking to U.S. agencies in the international arena; and to distinguish clearance from regulatory issues on import of orphan sources and illicit trafficking of nuclear materials.

B. INTRODUCTION

The importance of clearance regulations internationally is the legal acceptance of imports and exports. Differences in clearance criteria among countries could adversely affect international trade. International acceptability of cleared materials and equipment is based on what is referred to in the international scientific community as "established trivial doses and risks"[1] (see "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control," IAEA Safety Series No. 89, 1988). The National Council on Radiation Protection and Measurements (NCRP) refers to these levels as a "negligible individual dose." Regulatory issues concerning orphan sources and illicit trafficking of radioactive materials are distinct, but overlap with clearance issues, because they involve the detection of radioactivity associated with materials and equipment moved across national boundaries. Clearance is distinguished from orphan sources and illicit trafficking because the release from regulatory control for clearance is intentional and is based on a trivial dose.[2] International aspects of clearance and these overlapping issues are briefly addressed below.

C. INTERNATIONAL STATUS OF CLEARANCE LEVELS

A number of countries have adopted and implemented clearance levels. The concentrations of radionuclides and conditions for clearance vary among countries. However, there are two important international activities that will tend to harmonize clearance internationally. They are the activities of the International Atomic Energy Agency (IAEA) and the European Commission (EC). Many of the countries that have clearance levels are in the EC, and those countries have been directed to conform with EC recommendations by May 13, 2000. Staff is aware of at least two countries, Germany and the U.K., that are expected to be in full or virtually full compliance by that date. Other countries likely will apply for extensions of the deadline before their full compliance. Principal countries outside the EC that could clear materials and equipment generally may be expected to follow the EC. Significant amounts of cleared materials and equipment might be expected in the form of products imported from Canada, Japan, and former-

[1] The economic and societal acceptability of cleared materials and equipment are somewhat related through cost/benefit and optimization analyses, but they are not central to the regulatory establishment of a trivial dose from materials and equipment.

[2] Six major international organizations defined clearance as, "Removal of radioactive materials or radioactive objects within authorized practices from any further control by the Regulatory Authority." They are the: Food and Agriculture Organization of the United Nations (FAO); International Atomic Energy Agency (IAEA); International Labor Organization (ILO); Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA); Pan American Health Organization (PAHO); and World Health Organization (WHO), (International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna, 1996; (BSS)).

Soviet-Union countries. The background and status of the activities of the IAEA and the EC are briefly described below in relationship to the NRC efforts in the area of clearance.

The concept of clearance was established by the IAEA in its Basic Safety Standards (BSS). Although the IAEA BSS does not clarify the implementation of clearance, there has been progress internationally by the IAEA and the EC and nationally in a number of countries. The consistent threads among these efforts are that "on the order of 10 μSv/a[3] for a practice" is a trivial dose, 1 man-Sv[4] per year of practice or less requires no further analysis for optimization (ALARA), and "clearance" means the total cessation of radiological control.

The IAEA has already published an interim report for the implementation of clearance. It used the 10 μSv/a criterion and pathway analyses from a number of countries to translate the dose criterion to concentrations of radioactivity distributed on surfaces (Bq/cm^2) and throughout volumes (Bq/g). These clearance levels, in units of Bq/cm^2 and Bq/g, for each radionuclide, are the measurable quantities required for the implementation of the clearance criterion (10 μSv/a). The clearance levels were presented in ranges because of the associated uncertainties, and the values are intended to apply to all materials or equipment. The report was issued in 1996 as an interim, TECDOC-855,[5] at the request of some member states, including the U.S. Both the EPA and the NRC wanted to complete their respective, independent pathway analyses so the U.S. could have substantive technical input. Now, the IAEA wants to finalize the clearance levels as a result of a number of technical meetings, getting input from the U.S. and other countries, refinements in methods of modeling, and comments on the interim IAEA report. Publication of the IAEA clearance levels is unlikely before 2001.

The progress of the EC in the area of clearance appears to be a significant driver for the IAEA. The EC published exemption values in 1993,[6] and established clearance criteria, among other things, in a May 13, 1996, Euratom Council Directive.[7] This Directive establishes as a basis for clearance 10 μSv/a to individuals and an automatic (no further consideration required) optimization level ("floor" to ALARA) of 1 man-Sv per year of practice, and requires Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before May 13, 2000.

The EC has published or has in press implementation recommendations that translate the 10 μSv/a dose level to concentrations of radionuclides. Based on pathway analyses of steel, copper, and aluminum, Radiation Protection 89, "Recommended radiological protection criteria for the recycling of metals from the dismantling of nuclear installations," provides clearance levels for recycling of all metals. Radiation Protection 113, "Recommended radiological protection criteria for the clearance of buildings and building rubble arising from the dismantling of nuclear installations," is in press, and EC clearance of buildings is based on the trivial dose level, namely, 10 μSv/a. "Practical Use of the Concepts of Clearance and Exemptions–Part 1, Guidance on General Clearance Levels for Practices," (in draft) provides general clearance

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[3] 10 μSv/a is equivalent to 1 mrem/y.

[4] 1 man-Sv is equivalent to 100 man-rem.

[5] Clearance levels for radionuclides in solid materials: Application of exemption principles; Interim report for comment, IAEA-TECDOC-855, IAEA, Vienna, January 1996.

[6] These exemption values were also adopted by the IAEA. Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) below Which Reporting Is Not Required, European Directive, Radiation Protection 65, Doc. XI-028/93, CEC, Brussels, 1993.

[7] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. Official Journal of the European Communities L 159 of 29.6.1996.

levels that are applicable to all materials and equipment. Part 2 of this document will address clearance of materials and equipment with associated radioactivity from natural sources (NORM), since the EC Directive also addressed significant increase in exposure due to natural radiation sources.

The EC approach for deriving clearance levels differs significantly from the NRC and EPA approaches. The NRC and EPA both analyze external exposure, inhalation, and ingestion pathways and generally sum them to get the values that enable translation from dose to radionuclide concentration. The American agencies use Federal Guidance Report Nos. 11 and 12, which are based on ICRP 26 and 30 for dose conversion. The EC uses ICRP 60 (1990) dose conversions, analyzes the same pathways plus skin exposure and separately analyzes doses to children. However, the EC does not sum the pathways to derive the clearance level, since the models are already conservative and analysis reveals that nearly all the dose comes from only one pathway in virtually all scenarios. Thus, the EC uses the most restrictive of the pathways examined. The IAEA has adopted the EC approach for the finalization of their clearance levels.

D. RELATIONSHIPS OF AN NRC CLEARANCE RULEMAKING TO U.S. AGENCIES IN THE INTERNATIONAL ARENA

At least four other Federal agencies would likely be impacted by an NRC rulemaking: the Department of Defense (DOD); the Department of Energy (DOE); the Department of Transportation (DOT); and the Department of the Treasury (Customs Service). The Environmental Protection Agency (EPA) has responsibility for setting generally applicable environmental standards under the Atomic Energy Act. Although EPA is not pursuing a rulemaking in this area at this time, they are continuing to develop a technical data basis for estimating potential doses resulting from release of solid materials. In addition, the EPA is working with the U.S. Department of State regarding the international standards setting. The military services control radioactive materials in many foreign countries. Harmonization of the local clearance levels and U.S. clearance levels would simplify the management. The DOE has, as of January 12, 2000, instituted a moratorium on release of metals with volumetric residual radioactivity. Historically, the DOE has established its orders and regulations in conformance with NRC regulations. If the precedent were to continue, an NRC regulation would indirectly impact, among other things, the ability to export DOE materials. Transportation regulations are well established internationally. Clearance levels would need to comply with those regulations or the international regulations would require modification. Finally, the Customs Service would be impacted in their decisions to allow or reject imports with detected radioactivity.

E. OVERLAPPING INTERNATIONAL ISSUES

In the context of import and export, potential failures of adequate radiological protection can occur in a variety of ways. Intact orphan sources, shielded or unshielded, can be mixed in shipments of, for example, scrap and salvaged materials from industry. Another way is through the import or export of materials or equipment with concentrations of radioactivity ranging from hundreds of times that of clearance levels to very high concentrations. This situation can arise from several circumstances, for instance: incorporation of orphan sources by processing, including melting; activation products in materials and equipment; NORM at natural levels, concentration of NORM or other radionuclides by natural or man-made processes. Finally, there is a concern for the illicit trafficking of fissile materials.

The regulatory mechanisms to provide an adequate level of protection from relatively high concentrations of radionuclides in imports has yet to be developed.[8] The regulatory emphasis may be best spent on international requirements that control the potential for exposures above the public dose limit. In a Memorandum of Understanding, "Establishment of Radiological Screening Guidelines for the Free Release of Metal Products for Export to the United States," signed September 2, 1998, and October 29, 1998, respectively, the EPA and the Department of State initiated efforts to address this issue internationally.

Other Federal Agencies, including the NRC and DOE, and industry were then invited to participate in a committee–the International Radioactive Source Management Committee (IRSM). The initiative had four mission objectives: 1) protect sources from becoming lost (tracking management); 2) identify primary location where sources have been lost (stopping future losses); 3) locate lost sources (monitor and retrieve); and 4) educate and train (deploy knowledge and technology). This would involve domestic and international partnerships among various entities including the IAEA, Western Europe, and the Americas. Along these same lines the IAEA has formulated an action plan to control radioactivity, and on October 1, 1999, the General Conference adopted the action plan. In addition, the European Commission recently decided to elaborate a directive to prevent orphan sources. The first preliminary draft defines responsibilities of holders of sources, users, manufacturers, and describes financial provisions for disposition of orphan sources.

On December 1, 1999, each subcommittee of the IRSM made presentations to Mr. Abel Gonzales of the IAEA, and Mr. Gonzales identified how the U.S. could assist in international efforts to control orphan sources. The IAEA has scheduled an "International Seminar on Implementation of Systems to Prevent and Detect Unauthorized Uses of Nuclear and Radioactive Materials," in Vienna, Austria on November 13-17, 2000.

The Department of State has focused its resources on the Non-Proliferation Treaty Review Conference. After the conference ends on May 20, 2000, the Department of State will re-direct attention to the IRSM and the U.S. support of international efforts in this area.

F. RECENT AND FUTURE IAEA MEETINGS ON CLEARANCE LEVELS

1) February 14-18, 2000: Technical Consultants' Meeting on Clearance levels for solid materials

2) June 26-30, 2000: Consultants' Meeting for redrafting the annex, "Clearance Levels for Solid Materials," to the Safety Guide

3) October 16-20, 2000: Technical Consultants' Meeting on Clearance levels for solid materials

[8] By definition, cleared materials and equipment are not controlled, and for radiation protection purposes, they need not be controlled, because the potential doses are a small fraction of the public dose limit that, in turn, defines an adequate level of protection.