March 1, 1999

FOR: The Commissioners

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

SUBJECT: NUCLEAR BYPRODUCT MATERIAL RISK REVIEW

PURPOSE:

To inform the Commission of the staff's approach for identifying and documenting a methodology for determining a technical basis for risk-informed decisions on the regulation of nuclear byproduct material (i.e., risk assessment) and for developing plans for a graded approach to nuclear byproduct material regulation based on risk information (i.e., risk management). The nuclear byproduct material risk assessment is one piece of the overall approach described in a separate Commission paper, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards."

SUMMARY:

This paper addresses Commission direction transmitted by an April 15,1997, Staff Requirements Memorandum (SRM) related to Direction Setting Issue 12 (DSI-12): "Risk-Informed, Performance-Based Regulation" (see Attachment 1) and Commission direction transmitted by an April 13, 1998, SRM related to "Improving NRC's Control Over, and Licensees' Accountability for, Generally and Specifically Licensed Devices" (see Attachment 2). In response to those SRM's, the staff has initiated a process for development and implementation of a risk analysis methodology appropriate to the systems regulated under 10 CFR Parts 30-36 and 39. Pursuant to the Commission's request, this paper provides information about the current status and products of that effort. This paper also describes those steps necessary to assure a firm foundation for application of the risk assessment methodology to materials systems, use of the risk assessment methodology to explore the impacts of various regulatory options, and integration of the results of the risk assessment activities into the Office of Nuclear Material Safety and Safeguards (NMSS) ongoing effort to establish a framework for risk management.

BACKGROUND:

In an April 15,1997,SRM the Commission indicated that, in the future, the regulatory focus should be on those licensee activities that pose the greatest risk to the public. It further indicated that accomplishment of that focus would depend on increased use of probabilistic risk assessment concepts or other approaches that would allow a graded approach for determining high- and low-risk activities. The staff was directed to identify and prioritize areas of nuclear material regulation that were, or could be made amenable to, risk-informed, performance-based, or risk-informed, less-prescriptive, approaches, with minimal additional staff effort/resources.

Subsequent to initiation of staff activities in response to the SRM on DSI-12, the Commission further directed that the staff use the results of its activities to restructure current licensing and materials programs and, in particular, to consider the findings when determining whether additional sources/devices should be subject to registration and follow-up.

Part of the staff's response to the SRM on DSI-12 was the establishment of a Nuclear Regulatory Commission (NRC)/Agreement State Working Group, referred to as the Nuclear Byproduct Material Risk Review Group (hereafter called NBMRRG). The scope of NBMRRG's activities was to encompass byproduct materials as defined in Section 11.e(1) of the Atomic Energy Act of 1954 and regulated under Title 10 of the U.S. Code of Federal Regulations, Parts 30-36 and 39. NBMRRG's goals were to identify and document a technical basis for a risk-informed approach to regulation of materials within its scope and to develop plans for a graded approach to regulation of that material using risk information. NBMRRG's approach was to obtain systematic evaluations of the "nuclear byproduct material systems" that fell within the scope of its efforts. Each system was to be characterized in terms of risk to workers and the public under normal and off-normal conditions. Existing and potential approaches and regulatory positions for addressing the risk associated with the nuclear byproduct material systems were to be identified and evaluated, and a model for a graded approach to regulation, including licensing and inspection, was to be developed. The evaluation was to include cost-benefit analyses comparing the model for a graded approach with the existing approaches.

The April 15, 1997 SRM also directed the staff to develop a framework for applying probabilistic risk assessment (PRA) to all nuclear material uses, including byproduct materials in review by NBMRRG, similar to the framework developed for application of PRA to reactor regulation. The staff concluded that the reactor framework using PRA was not directly applicable to all of the activities regulated by the Office of Nuclear Materials Safety and Safeguards (NMSS). The staff also concluded that the tasks of NBMRRG could not be fully addressed until such a framework was developed. A separate task group was assembled to (1) develop an appropriate framework of risk assessment methods for regulation of NMSS materials, and (2) make a preliminary identification of how the association risk assessment method could be used in a risk-informed regulatory framework for nuclear materials regulation. The work of this task group is contained in the Commission paper, "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards."

DISCUSSION:

At the outset of its task, NBMRRG recognized the challenge presented by the diversity of materials, activities, and uses of the byproduct materials within its scope. NBMRRG also recognized the challenge presented by the variability in the way that use of nuclear byproduct material was regulated. In response to those challenges, NBMRRG chose to organize the risk assessment and development of regulatory options on the basis of systems. That

approach attempted to categorize similar uses, types, forms, and quantities of materials, together, regardless of the current regulatory basis. A preliminary list of such systems was developed at the outset of the risk assessment and has continued to be refined as the assessment progressed (see Attachment 3).

Major efforts after developing the preliminary list of systems, included:

1. Obtaining the services of a contractor to assist the review group;

2. Directing the contractor's efforts to develop and implement an approach to risk assessment that was appropriate for material systems;

3. Documenting the bases (e.g., regulations, guidance, good practices) for existing barriers and administrative controls that work to limit worker and public exposure to radiation from nuclear byproduct material systems; and

4. Surveying materials licensing and inspection personnel on typical worker doses; typical events and frequencies; perceptions of safety; materials and quantities typical of various systems; the existence and value of various barriers to dose; and the value of particular regulatory options.

Risk assessment methodology. A working draft of the contractor's report on development and implementation of a risk assessment methodology for nuclear byproduct material systems is provided as Appendix 1 to a report by NBMRRG (see Attachment 4). After review of the working draft, NBMRRG concluded that the approach developed by the contractor had a number of potential strengths. Among the more important of the potential strengths were its provision of a structured and repeatable risk methodology, its ability to provide risk metrics for workers and the public under normal and off-normal conditions, its provision of a risk metric for lost sources, and its ability to focus on the highest-priority safety functions and regulatory options in managing the risk associated with each system. Additional potential strengths of the risk assessment methodology are listed in the aforementioned Attachment 4.

NBMRRG also identified a number of concerns with the risk assessment developed and implemented by the contractor. One major concern was whether the risk methodology developed by the contractor was appropriate (i.e., was capable of providing reasonable and useful estimates of the radiological risk of materials systems). To confirm its appropriateness, NBMRRG arranged for a peer review of the methodology by Dr. Charles Meinhold of the National Council on Radiation Protection and Measurements. Dr. Meinhold's comments on the contractor's risk assessment methodology are provided as Attachment 5. Those comments support a conclusion that the risk assessment methodology is appropriate for materials systems. Other major concerns involved: the completeness and accuracy of the system descriptions; the assumptions about system operation that were used as input to the individual risk assessments; the fact that only 26 of the approximately 40 nuclear byproduct material systems were analyzed using the contractor's quantitative (i.e., probabilistic) methodology; the extent of the uncertainty associated with the risk assessment of some systems; and the possibility that the current definitions of some systems are too broad to allow development of appropriate regulatory options across their full range. Additional concerns about the risk assessment methodology are listed in Attachment 4.

The majority of the concerns with the risk assessment methodology appeared to be the result of the limited time, resources and information available. In most cases, results for a given system are reported with an uncertainty of at least an order of magnitude, usually due to lack of data or completeness of detail; overall, the systems risks range over six orders of magnitude. [To date, the effort has resulted in: (1) development of a sophisticated risk assessment methodology that can be applied to a wide range of systems; (2) the collection of information that describes the majority of the nuclear byproduct material systems and their operation in those terms required as input to the risk assessment; (3) implementation of the full risk assessment methodology for 26 of those systems; (4) implementation of a less complete risk assessment for the remaining systems; (5) prioritization of safety functions, in terms of risk, for 26 systems; and (6) development of regulatory options directed toward management of the risk associated with those 26 systems.] Resolution of the major concerns with the risk assessment can be addressed in part by completing quantitative analyses of all systems -- including subdividing several systems that, as currently defined, are too broad for results to be useful -- and by a combination of in-house technical and public review to assure that input to the risk assessment methodology is adequate. Attachment 6 provides a schedule for completion of those activities. This schedule does not address information collection to improve the uncertainties due to the limitation of data available.

Bases for barriers. Beginning with sets of contractor-identified barriers (i.e., engineering and administrative controls) that work to limit worker and public exposure to radiation from the nuclear byproduct material systems, NBMRRG identified the existing bases for those barriers (e.g., good practices, license conditions, and regulations intended to assure that barriers are in place). That information was documented in a draft report provided as Appendix 2 to Attachment 4. When finalized, the information in that document can serve as a basis for comparing current barriers and their bases with those barriers identified as important by the contractor. NBMRRG is concerned about the completeness of the draft listing of barriers and their bases. Resolution of that concern will involve peer and public review of the draft report on barriers. The schedule for those activities is included in Attachment 6 to this paper.

Survey of materials licensing and inspection personnel. NBMRRG conducted a survey of NRC and Agreement State licensing and inspection personnel. The survey asked about typical worker doses, typical events and frequencies, perceptions of safety, materials and quantities typical of various systems, the existence and value of various barriers to dose, and the value of particular regulatory options. A draft summary of the results of that survey are provided as Appendix 3 to Attachment 4. The survey was system-based and linked to the systems assessed by the contractor. Survey results concerning annual worker dose and events associated with individual systems will be available for comparison with similar data developed for the contractor's risk assessment. Marked differences for any system may indicate the need for improving knowledge of that system. Results concerning the safety of the various systems are expected to provide a broader perspective about what is required to manage the risk associated with the various systems. Other survey results can also be compared with the results of the contractor's risk assessment. The staff has committed to the Organization of Agreement States to make draft results of the survey available for public review and comment. The schedule for those activities is included in Attachment 6 to this paper.

Next Steps. To date the activities of the staff have focused on development and implementation of a methodology for assessing the risks associated with nuclear byproduct material systems.

Although there are concerns, the risk methodology that has been developed has the potential to provide very useful information about the risks associated with byproduct materials systems as they exist under current regulations. The staff plans to resolve identified concerns with the risk methodology through the process outlined in Attachment 6. The staff then plans to use the risk methodology to evaluate various regulatory options in terms of risk and burden to licensees and regulatory bodies.

Finally, the staff plans to integrate the results of the risk assessments of materials systems as they currently exist, and as those systems might exist if various regulatory options were exercised, with ongoing NMSS activities to establish a framework for risk management. The byproduct materials activities reviewed by NBMRRG are the same as the "Group 4" regulated uses of nuclear materials defined by the framework task group. The work of this task group is contained in the Commission paper "Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards". For the Group 4 uses, the nuclear materials byproduct risk assessment will provide: development and application of a modified hazard/barrier risk assessment method, risk assessment results using annual whole body dose as the risk metric, recommendations for regulatory approaches for several categories of accident consequences, and peer review of these issues. This information supports, in part, Step 1 (identification of specific regulatory applications that would be amenable to risk-informed regulatory approaches), Step 2 (modification of current regulatory approaches), and Step 5 (development of needed tools for risk assessment) of the implementation of the proposed framework for nuclear materials uses and disposal.

RESOURCES:

The staff estimates that continuation of the nuclear byproduct material risk review, as discussed above, will require additional resources of $500,000 and approximately 1 full-time equivalent position each year in FY 1999 and FY2000, which are not currently budgeted. The necessary resources will be accommodated within the budget by reprogramming funds from currently planned activities.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. There is no information technology impact that would result directly from this paper.

William D. Travers
Executive Director for Operations

CONTACTS: Patricia K. Holahan, NMSS/IMNS
(301) 415-8125
Betsy Ullrich, RI/DNMS
(610) 337-5040

Attachments:

1. SRM Dated 4/15/97
2. SRM Dated 4/13/98
3. List of Byproduct Systems
4. Dec. 1998 RRG Report (Appendices 1, 2 & 4 to Commissioners and SECY only)
5. Letter from Charles Meinhold dated 12/15/98
6. Preliminary Schedule

ATTACHMENT 3

LIST OF SYSTEMS AS USED IN THE SURVEY OF NUCLEAR REGULATORY COMMISSION AND AGREEMENT STATE MATERIALS LICENSING AND INSPECTION PERSONNEL(1)

1. Research and development synthesis laboratories
2. Research and development laboratories using carbon, hydrogen, iodine, phosphorous, and sulfur
3. In-vitro laboratory testing
4. 10 CFR 35.100 - nuclear medicine and human use research
5. 10 CFR 35.200 - nuclear medicine with generator(s)
6. 10 CFR 35.200 - nuclear medicine without a generator
7. 10 CFR 35.300 - nuclear medicine
8. Brachytherapy using seeds

9. Brachytherapy - manual afterloading
10. Brachytherapy - low dose rate remote afterloading
11. Brachytherapy - high dose rate remote afterloading
12. Brachytherapy - eye applicator
13. 10 CFR 35.500 - diagnostic devices
14. Teletherapy devices
15. Gamma stereotactic surgery
16. Nuclear pharmacies
17. Veterinary use
18. R&D on animals
19. Well logging - tracers and field flood studies
20. Well logging - using sealed sources
21. Radiography - permanent installation
22. Radiography - field use
23. Pool irradiators
24. Self-shielded irradiators
25. Fixed gauges - gamma emitters
26. Fixed gauges - beta emitters
27. Portable gauges
28. X-ray fluorescence devices
29. Gas chromatographs
30. Other measuring devices
31. Small sealed sources or devices (e.g., those used under a general license)
32. Very small sealed sources or devices (e.g., those used under an exemption)
33. Manufacturing or distribution of devices containing sealed sources
34. Manufacturing of sources containing solids
35. Manufacturing of sources containing liquids
36. Manufacturing of sources containing gases
37. Incineration of waste
38. Compacting of waste
39. Packaging of waste
40. Solidification of waste

ATTACHMENT 4

DECEMBER 1998 REPORT OF THE NUCLEAR BYPRODUCT MATERIAL RISK REVIEW GROUP

1. BACKGROUND

One of the Direction Setting Issues (DSIs) in the Commission's Strategic Assessment and Rebaselining initiative was "Risk-Informed, Performance-Based Regulation" (DSI-12). The Commission transmitted its views on the matters discussed in DSI-12 to the staff in an April 15, 1997, Staff Requirements Memorandum (SRM). The SRM expressed the Commission's general view that:

1. To accomplish the principal mission of the Nuclear Regulatory Commission (NRC) in an efficient and cost-effective manner, it will, in the future, have a regulatory focus on those licensee activities that pose the greatest risk to the public;

2. This focus can be accomplished by building upon probabilistic risk assessment (PRA) concepts, where applicable, or other approaches that would allow a risk-graded approach for determining high- and low-risk activities; and

3. The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports NRC's traditional defense-in-depth philosophy.

With respect to activities within the purview of the Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, the April 15, 1997, SRM related to DSI-12 stated:

> The staff should . . . reexamine the applicability of its risk-informed, performance-based or risk-informed less prescriptive approaches with regard to nuclear material licensees . . . , to ensure that the needs of those licensees . . . receive adequate consideration. The staff should perform a review of the basis for the nuclear materials regulations and processes, and should identify and prioritize those areas that are either now, or could be made, amenable to risk-informed, performance-based or risk-informed less prescriptive approaches with minimal additional staff effort/resources. This assessment should eventually lead to the development of a framework for applying PRA to nuclear material uses, similar to the one developed for reactor regulation (SECY-95-280), where appropriate.

Subsequent to the SRM related to DSI-12 and to initiation of staff activities to respond to that SRM, the Commission issued an SRM related to "Improving NRC's Control Over, and Licensee's Accountability for Generally and Specifically Licensed Devices." That SRM implicitly acknowledged initiation of staff actions in response to the SRM related to DSI-12 and stated:

Use the results of the materials risk assessment study to restructure the current licensing and materials programs. Consider the findings when determining whether additional sources/devices should be subject to registration and follow-up, and for performing the risk ranking necessary if a phase-in approach is used to reduce the initial resource surge associated with an increased regulatory program. Review the basis of the general licenses for adequacy with respect to consideration of the consequences of off-site accidents, such as loss of shielding or melting in metal-making furnaces. The staff should provide the technical basis document for the risk assessment together with recommendations on how to proceed.

Among the staff's responses to the SRM related to risk-informed, performance-based regulation, was establishment of an NRC/Agreement State Working Group. This was known as the Nuclear Byproduct Material Risk Review Group(hereafter the Group), and included John Lubinski, John Randall, and Dennis Serig from NRC Headquarters, Elizabeth Ullrich from NRC Region I, and Nancy Daugherty from the Agreement State of Colorado. The Group's expertise encompassed health physics, mechanical engineering, risk and reliability engineering, byproduct material licensing and inspection, and human factors.

The scope of the Group's efforts was to encompass byproduct materials as defined in Section 11.e(1) of the Atomic Energy Act of 1954, and Title 10 of the U.S. Code of Federal Regulations (CFR) Section 30.4, and addressed by 10 CFR Parts 30-36 and 39. The Group's goals with respect to those materials were to:

1. Identify and document a technical basis for a risk-informed approach to the regulation of nuclear byproduct material; and

2. Develop plans for a graded approach to nuclear byproduct material regulation, based on risk information.

The Group's approach was to obtain systematic evaluations of the "nuclear byproduct material systems" that fell within the scope of its efforts. The nuclear byproduct material systems were to be defined as broadly as necessary, to identify the real-world risks associated with them. The approach was to be an iterative process and was intended to include:

1. A multi-dimensional characterization of risk associated with nuclear byproduct material systems in the form of a matrix that would allow ranking of those systems in terms of low, medium, and high risk. This would include consideration of risk factors to be taken into account when regulating byproduct material such as doses to occupational workers and the public and the likelihood (probability) and potential severity (consequence) of events (including contamination cleanup).

2. Use of qualitative and, to the extent possible and reasonable, quantitative tools to identify and evaluate risks associated with nuclear byproduct material systems and development of an analytical risk-ranking model by applying the criteria developed in 1, above, to categorize each system.

3. Identification and evaluation of existing and potential technical approaches and regulatory positions for addressing the risk associated with nuclear byproduct material systems.

4. Integration of the analytical risk-ranking model with the identified technical and regulatory positions into a model for a graded approach to regulation, including licensing and inspection.

5. Cost-benefit analyses comparing the model for a graded approach to regulation with the existing approach to regulation.

The Group initiated a number of actions intended to provide the information necessary to meet its goals. The first was to evaluate the scope of Section 11.e(1) (of the Atomic Energy Act of 1954) activities encompassed by the effort and to develop a preliminary list of approximately 40 "systems" (see subsequent discussion). The second action was to develop a statement of work and request for proposals and to select a contractor to refine the preliminary list of systems and to develop and implement an appropriate risk assessment methodology. The third action was to monitor the progress of the contractor in development and implementation of a risk assessment of the approximately 40 systems determined to fall within the scope of 11.e(1) activities. Monitoring of the contractor's efforts identified the need for the staff to provide substantial assistance regarding 11.e(1) activities. That assistance included identification and documentation of current means for supporting barriers intended to limit worker and public exposure to radiation from nuclear byproduct material systems (e.g., regulations, license conditions, guidance, good practices, etc.). The fourth action was to develop, implement, summarize, and evaluate the responses to a survey of NRC and Agreement State materials licensing and inspection personnel regarding the safety of the nuclear byproduct material systems. A working draft of the contractor's report on development and implementation of the risk assessment methodology for nuclear byproduct material systems is provided as Appendix 1 to this report. Drafts of the Group's identification of current barriers intended to limit worker and public exposure to radiation from nuclear byproduct material systems and the Group's summary of responses to its survey of NRC and Agreement State materials licensing and inspection personnel are provided as Appendices 2 and 3 to this report.

2. DISCUSSION

At the outset of its activities, the Group recognized the diversity of types, forms, and quantities of nuclear byproduct materials encompassed by Section 11.e(1) of the Atomic Energy Act of 1954. For example, unsealed materials are typically used in microcurie or millicurie quantities in laboratories and in nuclear medicine. Sealed sources may be found in microcurie or smaller quantities as calibration sources and in products such as wrist watches and smoke detectors, in millicurie quantities in devices such as gas chromatographs and portable gauges, and in curie quantities in devices such as tritium exit signs, fixed gauges, radiography devices, and medical devices. The Group also recognized the diversity of approaches to regulation of nuclear byproduct materials. All specific licensees regulated by NRC must comply with the requirements of 10 CFR Part 19 (notices, instructions, and reports to workers); 10 CFR Part 20 (standards for protection against radiation); and 10 CFR Part 30 (rules of general applicability . . .). Manufacturing, radiography, medical uses, panoramic irradiators, and well-logging are also addressed by dedicated parts of 10 CFR (Parts 32, 34, 35, 36, and 39, respectively). Those chapters describe regulations for specific licensing of the subject's uses of nuclear byproduct materials. In addition, Part 32 requires that the design for all devices and sealed sources be reviewed and registered before distribution.

The Group also recognized that some devices incorporating nuclear byproduct materials, usually as sealed sources, are exempt from the regulatory requirements of 10 CFR. Other devices incorporating nuclear byproduct materials, again, usually as sealed sources, are generally-licensed and are subject to only limited requirements under certain sections of 10 CFR Part 31 and, for some uses, referenced sections of Parts 19, 20, or 30. Some States require registration of some types of generally licensed devices. The issue of differing approaches to regulation is further confused by the fact that some devices incorporating nuclear byproduct materials, such as gas chromatographs, fixed gauges, and in-vitro kits, may, depending on minor variations in design or who the user is assumed to be, be either specifically-or generally-licensed.

Given the diverse uses, quantities, and approaches to regulation, the Group chose, as noted above, to organize the risk assessment on the basis of systems. That approach attempted to categorize similar uses, types, forms, and quantities together, regardless of the current regulatory basis. Those systems were not bounded by the way nuclear byproduct materials are currently regulated nor by what various "types" of licensees do with the nuclear byproduct materials that they possess. Any licensee may use nuclear byproduct materials from one or more systems. For example, medical licensees may use unsealed materials for diagnostic scans (Systems 4 and 5 in the contractor's report; Systems 5 and 6 in the Group's survey of NRC and Agreement State materials licensing and inspection personnel), and may simultaneously have self-shielded irradiators (System 21 in the contractor's report; System 24 in the Group's survey of NRC and Agreement State materials licensing and inspection personnel) for sterilization of blood, small sealed sources for calibration of instruments (System 29 in the contractor's report; System 31 in the Group's survey of NRC and Agreement State materials licensing and inspection personnel), and a laboratory where in-vitro testing is performed (System 3 in both the contractor's report and the Group's survey of NRC and Agreement State materials licensing and inspection personnel).

The risk assessment required description of each of the nuclear byproduct material systems. It was recognized that, as implemented, those systems reflected past and current regulatory positions and practices (e.g., rules, license conditions, guidance) as well as good practices developed by users over the years. Thus, it was inevitable that accurate descriptions of the systems would also reflect current and past regulations and good practices. It was also recognized that there was variability in the way that some of the nuclear byproduct material systems were regulated. For example, the nickel-63 sealed source in an electron capture detector used in a gas chromatograph (System 27 in the contractor's report; System 29 in the Group's survey of NRC and Agreement State materials licensing and inspection personnel) may be generally- or specifically-licensed, depending on variations in design. However, because the basic designs of the generally- and specifically-licensed devices, as well as the use of the material, are similar, many of the barriers intended to limit radiation exposure from the devices, regardless of how they are licensed, are similar. The risk assessment approach for such systems was intended to be free of consideration of variations in the ways that they were regulated. Thus, regardless of any variations in the way a system was regulated, the description and risk analysis of that system were to include consideration of all the barriers typical to that system. Similarly, the exploration of regulatory options for a system was to identify those barriers necessary and sufficient to maintain doses at specified levels without regard to the current approach or approaches to regulation of that system.

Contract efforts. Scientech, Inc., was awarded a contract to assist the Group on December 31, 1997. Scientech's tasks included:

1. Developing a risk assessment methodology that could be applied to each of the systems; included within the scope of the review;

2. Acquiring information about each system in order to understand and describe its hazard(s), potential dose receptors, and the barriers that work to limit exposure of the receptors to the hazard(s), as well as other information needed to exercise the risk assessment methodology that was developed; and

3. Using information from the system descriptions and risk assessments to identify important barriers for each system and to identify regulatory options that would work to control risk by supporting those barriers.

A working draft report of the results of Scientech's efforts is provided as Appendix 1. The report describes the approach to risk evaluation developed by Scientech; provides a summary of the risk evaluation results for each system, including development of regulatory options; and summarizes results across all systems.

The Group has completed preliminary review of Scientech's working draft and has concluded that the approach developed for risk assessment of materials systems has a number of potential strengths. Among the potential strengths are:

1. Provision of a structured and repeatable risk methodology.

2. Provision of risk metrics for both worker and public under normal (i.e., all barriers and controls intact) and off-normal (i.e., one or more barrier breached) conditions;

3. Provision of a risk metric for lost sources;

4. Linkage of dose and risk information system to safety functions and to the barriers and administrative controls needed to support those functions;

5. Prioritization of safety functions (i.e., source strength, shielding, confinement, and access) with respect to risk;

6. Identification and prioritization of regulatory options that support the barriers and administrative controls necessary to manage risk;

7. Development of a structured, repeatable risk evaluation methodology;

8. Ability to perform sensitivity analyses;

9. Ability (given sufficient data) to perform uncertainty analyses;

10. Ability to define, evaluate, and develop regulatory options for subsystems of the current systems or of entirely new systems;

11. The possibility of identifying and evaluating the performance-based regulatory options.

12. A peer review of the methodology by Dr. Charles Meinhold of the National Council on Radiation Protection and Measurements, whose comments support a conclusion that the risk assessment methodology is appropriate for materials systems.

Despite the potential strengths of the risk evaluation methodology developed and implemented by Scientech, review of the draft report identified a number of concerns about the current status of that effort. Among those concerns are:

1. The level of understanding of the scope of the activities (i.e., the system description) for a number of systems does not yet appear adequate and the completeness and accuracy of the system descriptions may be questioned;

2. The impact of the limited quantity of available data relevant to the operation and risk of materials systems, and the impact of limited access to those data that do exist;

3. The impact of inconsistencies in, and the questionable quality of the data on, materials systems that are available;

4. Confidence in assumptions about the systems and scenarios describing their operation;

5. Large unquantified and/or unsupported uncertainties;

6. Linkage between the dose and risk metrics and the approach for identifying and prioritizing regulatory options; and

7. The possibility that, as currently defined, some of the nuclear byproduct material systems are so broad (e.g., encompass a range of material activities from microcuries to hundreds of curies) that consideration of multiple regulatory options would be appropriate; and

8. Lack of evaluation of whether current variations in the regulation of particular systems are appropriate.

9. Only 26 nuclear byproduct material systems were evaluated quantitatively, whereas the others were evaluated qualitatively or evaluation was deferred, awaiting the results of a separate study.

Given the identified concerns with the status of the contractor's efforts, the Group concludes that, although the potential of the approach has been demonstrated, that potential has not yet been realized to an extent sufficient to support regulatory decision-making. Several actions are needed to facilitate implementation of the methodology such that it can serve its intended function. The actions include:

1. Confirmation of the appropriateness and adequacy of the methodologies for risk evaluation and development of regulatory options through peer and public review (peer review completed December 17, 1998).

2. Confirmation and improvement of the data and assumptions about each system that are critical to the risk evaluation and development of regulatory options.

3. Quantitative evaluation of those systems currently evaluated qualitatively.

4. Improvement of the methodology and upgrade of the information and assumptions about the systems based on the review processes and quantitative evaluation of additional systems.

5. Evaluation of whether current variations in the regulation of particular systems are appropriate.

Basis for barriers. Beginning with sets of contractor-identified barriers (i.e., engineered and administrative controls) that work to limit worker and public exposure to radiation from the nuclear byproduct material systems, the Group identified the existing basis for barriers (e.g., good practices, license conditions, and regulations intended to assure that barriers are in place). Appendix 2 reports the results of that effort. The strengths of the current identification of support for barriers are:

1. The basis for current barriers in each system are identified; and

2. The current barriers and their current basis can be compared with the barriers identified by the contractor report.

Those strengths are balanced by several concerns. They are:

1. The completeness of the current listing of barriers; and

2. The completeness of the current listing of bases for barriers.

In the case of the basis for barriers, resolution of the concerns requires peer and public review of the current document for accuracy and completeness of identification.

Survey of materials licensing and inspection personnel. The Group conducted a survey of NRC and Agreement State materials licensing and inspection personnel. The survey was developed to confirm and augment information gathered by the contractor and to assist in development of plans for a graded approach to nuclear byproduct material regulation informed by risk. The survey asked about typical worker doses; typical events and frequencies; perceptions of safety; materials and quantities typical of various systems; the existence and value of various barriers to dose; and the value of particular regulatory options. The final contractor report will address most of those same areas, thus allowing comparison of results. The Group received 41 responses to its survey of licensing and inspection personnel. Twenty-two were from Agreement State personnel and 19 were from NRC personnel. Data from the responses were entered into a spread sheet for analysis. The spread sheet was modified, as data entry progressed, to accommodate the fullest possible range of responses (e.g., to expand coding of data to include responses that were not consistent with instructions, but that appeared to be useful). Comments that could not be entered into the spread sheet, but that could affect the data analysis, were noted.

The strengths of the survey were:

1. System-based, linked to systems assessed by the contractor and in the documentation of the basis for barriers intended to limit exposure;
2. Tapped professional opinions of NRC and Agreement State materials licensing and inspection personnel;
3. Asked about distribution of doses received by workers within a system;
4. Asked about perceived safety of systems;
5. Asked about basis for safety perceptions;
6. Permitted analysis of the respondents' views of safety;
7. Asked specifically about the types and quantities of radionuclides used in selected systems;
8. Asked about the perceived value of various regulatory options for selected systems;
9. Asked about opinions concerning issues related to the actions of regulatory agencies in decision-making;
10. Permitted respondents to indicate where they lacked sufficient knowledge to respond to a question; and
11. Accommodated responses beyond those anticipated by the design of the survey.

The weaknesses of the survey were:

1. Limited to professional opinions rather than to responses based on reference to documented sources of information;
2. Some questions asked respondents to imagine the effects of conditions that they could not have experienced (e.g., the safety of material systems in the absence of current regulations);
3. Several survey questions asked respondents to state their opinions about the "safety" of nuclear byproduct material systems without defining safety or providing a link between safety and risk; and
4. Variations in respondents' interpretations of "safe."

Results of the survey indicate consistency in the respondents' opinions about the distribution of annual doses to workers in the various nuclear byproduct material systems and their opinions about the safety of those systems. However, for the respondents, safety appears to include a number of dimensions beyond those that formally define risk (i.e., likelihood and consequence). With a few notable exceptions, ranking of systems based on an annual dose estimate for individual workers derived from the contractor's working draft report, and a ranking of the same systems, based on dose information obtained from the survey of NRC and Agreement State materials licensing and inspection personnel were fairly similar (see Appendix 3 for results of a preliminary comparison). A more complete discussion of the results of the survey is found in Appendix 4.

3. CONCLUSION

Consistent with the Commission's direction in the April 15, 1998, SRM related to DSI-12, the staff has initiated a process intended to place appropriate regulatory focus on the activities of materials licensees that pose the greatest risk to the public. That initiative includes development and implementation of a risk assessment methodology appropriate to materials systems and review of the basis for nuclear materials regulations. In the staff's judgment, the initiative has the potential for identification of those areas that are either now, or could be made, amenable to risk-informed, performance-based, or risk-informed, less-prescriptive approaches to regulation.

Consistent with the Group's charter, draft documents identify the basis for current regulation of nuclear byproduct material systems and document a technical basis for a risk-informed approach to the regulation of nuclear byproduct material. The group did not develop plans for a graded approach to nuclear byproduct material regulation, but the results of the quantitative risk assessments of nuclear byproduct materials activities can be used for this purpose when appropriate context is provided by NMSS's risk management efforts associated with DSI-12. Additional actions that are required in order to provide risk information that is adequate for use in the risk management effort include technical review of the systems for completeness and accuracy, review of the data and assumptions on which the risk assessments are based for an understanding of the certainty of the evaluation and to identify if additional data is needed, and completion of quantitative risk assessments for nuclear byproduct materials systems that have not been evaluated.

In the review Group's judgment, the next phase of the risk review activities should focus on resolution of identified concerns with the risk methodology and its implementation. Upon completion of those activities, the risk review should proceed to exploration of the impacts of various regulatory options on risk and on the burdens to licensees and regulators. Finally, the risk review should integrate the results of the risk assessments of systems, both as those systems currently exist and as they might exist if various regulatory options were exercised, with ongoing NMSS activities designed to establish a framework for risk management.

[remainder of attachment 4]

ATTACHMENT 6

PRELIMINARY SCHEDULE FOR COMPLETION OF THE NUCLEAR BYPRODUCT MATERIAL RISK REVIEW

March 1999	Complete in-house technical review of the working draft of the contractor's risk assessment.
	Complete in-house review of draft document on basis for barriers.
April 1999	Complete quantitative analyses of systems not yet analyzed quantitatively and of several subsystems of systems that are currently defined too broadly (defer quantitative analyses of systems addressed by Oak Ridge project on exempt devices and quantities until publication of draft report on that project in May 1999).
	Complete draft summary of results of survey of materials licensing and inspection personnel.
May 1999	Complete final draft of contractor report for public comment.
	Complete final draft of document on basis for barriers, or public comment.
June 1999	Publish draft contractor report, for public comment.
	Publish draft document on basis for barriers, for public comment.
	Publish draft summary of results of survey of materials licensing and inspection personnel, for public comment.
September 1999	Complete finalization of draft contractor's report, document on basis of barriers, and results of survey, based on public comments.
October 1999	Complete nuclear byproduct material risk review report, integrating results of the contractor effort, document on basis for barriers, and survey results into a consolidated risk assessment of nuclear byproduct material systems for incorporation into the Nuclear Materials Safety and Safeguards wide risk management effort associated with risk-informed and performance-based regulation.
	Publish final contractor's report as NUREG/CR.

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1. Currently there are minor variations in the lists of systems in the contractor's working draft report, the staff's documentation of barriers, and the survey of materials licensing and inspection personnel. The system lists in the contractor's final report and the staff's final report on barriers will be reconciled before completion of the risk review. Survey results will be interpreted with respect to that reconciled list of systems.