

# **National Materials Program Pilot Project One FINAL Report**

## ***Establishment of Priorities***

### **Executive Summary**

In August 2002, the Commission approved the implementation of a blending of the “current program” and the “Alliance” options recommended by the National Materials Program (NMP) Working Group through the initiation of five pilot projects. The attributes of the NMP and the Alliance are described in the final report of the NMP Working Group in May 2001. The pilots were undertaken jointly by NRC, the Conference of Radiation Control Program Directors, Inc. (CRCPD) and the Organization of Agreement States, Inc. (OAS).

NMP Pilot Project One was designed to examine how NRC and the Agreement States could collaborate in the establishment of priorities for a national regulatory agenda, including the sharing of resources and responsibilities for development of regulatory products in the NMP. The objectives of the project were to establish a process and understanding on how NRC and Agreement States can collaborate in the identification of work products and establishment of NMP priorities, including the involvement and participation of both groups in the process, and to demonstrate how decisions on implementing plans for materials program work could be shared by NRC and Agreement State programs.

To meet the above objectives, the Pilot Project One Working Group completed the following work products: (1) a process that NRC and the Agreement States could use to establish priorities for development of materials policy, rulemaking, and guidance documents; (2) a national priority list; and (3) a proposed framework. The Working Group tested the prioritization process and framework for implementation of an Alliance-based NMP which included recommendations on specific regulatory needs made to the Working Group’s Steering Committee. The Steering Committee was composed of NRC Directors of the Offices of State and Tribal Programs (STP), Nuclear Material Safety and Safeguards (NMSS), and Nuclear Security and Incident Response (NSIR); NRC Region I Division of Nuclear Materials Safety (DNMS) Director; the chairs of OAS and CRCPD (or their designees).

The Pilot Project One Working Group was composed of seven NRC and Agreement State representatives from the NRC Offices of STP, NMSS, and the Chief Financial Officer (OCFO), NRC Region III, and the Agreement States of Texas and Massachusetts. Approximately 1,986.5 total hours were spent on the project as of September 18, 2004.

Responses to the eight Success Measures described in SECY-02-0074 and discussions of process development and lessons learned are included in the report. The pilot project demonstrated that a coalition made up of NRC and Agreement States can produce products that can be used by both NRC and Agreement States. The project also demonstrated that NRC and Agreement States could collaborate in making decisions on implementing plans to address specific regulatory needs in the materials program. Although the scope of the pilot did not permit demonstration that the Alliance will be a sustainable program for the NMP in the future, the test of the process gave indications that such a sustainable program is possible.

## **BACKGROUND**

The NRC, OAS, and CRCPD collaborated in the development of five pilot projects which were provided to the Commission in SECY-02-0074, dated May 3, 2002. The five pilot projects were intended to provide additional information to help understand the feasibility and viability of the Alliance Option recommended by the NMP Working Group. An Alliance is a cooperative process between the Agreement States and NRC that includes the collaborative development of regulatory products and priorities to enhance the establishment of a consistent national program.

The current NMP reflects the collective programs and efforts of NRC and the Agreement States, with NRC assuming a strong leadership role and with active Agreement State participation. However, it does not provide a means for NRC and Agreement States to jointly establish a national regulatory agenda. Pilot Project One was designed to provide additional information on the establishment of priorities, and on the sharing of resources and responsibilities for the NMP.

## **DISCUSSION**

Pilot Project One was charged with involving both NRC and Agreement States in the establishment of priorities for development of materials policy, rulemaking, and guidance products in the materials programs. Working Group members were identified and appointed by NRC management and the Boards of CRCPD and OAS who could provide varying perspectives that should be considered in establishing joint priorities. The NRC staff assigned to the Working Group represented the offices that could address materials regulation, budget, State and Tribal coordination, and regional perspectives. The State members assigned to the Working Group have managerial roles in overseeing materials programs in their respective states and have experience in evaluating collective State perspectives on regulatory issues. The following is a list of members on the working group:

Shawn R. Smith, Co-Chair	NRC STP
Ruth E. McBurney, Co-Chair	Texas Department of Health
Kimberly Farrell	NRC OCFO
Jayne Halvorsen	NRC NMSS
James Lynch	NRC Region III
Anita Turner	NRC NMSS
Robert Walker	Massachusetts Department of Public Health

The objectives of Pilot Project One were to:

1. Establish a process and understanding on how NRC and Agreement States can collaborate in the identification of work products and establishment of priorities for products needed in the materials program.
2. Demonstrate NRC's willingness to involve Agreement States to ensure that State needs are known and considered along with those identified by NRC staff in the establishment of national priorities for materials program work. Demonstrate willingness of the Agreement States to identify State needs and participate in a process to ensure that they

are known and considered along with those identified by NRC staff in the establishment of national priorities for materials program work.

3. Demonstrate how decisions on implementing plans for materials program work could be shared by NRC and individual Agreement States (e.g., how NRC and the Agreement States could reach agreement on respective responsibilities for completion of work products identified in a national priority list).

The project also focused on the following three specific scope of work areas:

1. Obtain information and develop understanding of the processes utilized by NRC and the Agreement States to establish work priorities for the materials program.
2. Examine and develop a process that could be utilized by NRC and the Agreement States in the establishment of priorities for development of materials policy, rulemaking, and guidance products.
3. Examine processes which NRC and the Agreement States could use to make decisions on implementing plans for materials program work and how that work would be shared by NRC and individual Agreement States (e.g., examine ways that NRC and the Agreement States could reach agreement on respective responsibilities for completion of work products identified in a national priority list).

### **Final Work Products**

In order to meet the above objectives, the Pilot Project One Working Group completed the following work products: (1) a process that NRC and the Agreement States could use to establish priorities for development of materials policy, rulemaking, and guidance documents, (2) a national priority list, and (3) a proposed framework.

- **Pilot Process**

In March 2003, the Working Group began to address its scope of work by examining current processes used by NRC and Agreement States in the establishment of priorities for development of materials policy, rulemaking, and guidance products. Through research, presentations, and interactive discussions with NRC staff, the Working Group obtained information and gained an understanding of how NRC and Agreement States can cooperate in the identification of regulatory work products to develop a national priority list. The Working Group developed a collaborative process which included the identification of regulatory needs and a prioritization process based on three performance goals: protection of public health and safety, security of radioactive materials, and efficiency and effectiveness. These specific three performance goals were chosen based on research conducted by the Working Group to determine how NRC and individual Agreement States prioritized regulatory needs in 2002. The research showed that the three performance goals were those commonly used by NRC and the majority of Agreement States in their processes to prioritize regulatory needs.

The Working Group overcame several challenges in its efforts to identify regulatory needs. One challenge was to define the scope of the regulatory needs for inclusion on the list. More specifically, the Working Group debated whether the list should include all radioactive material

or only material regulated by both NRC and Agreement States. After several discussions, the Working Group decided to include material for which both NRC and Agreement States have regulatory authority.

The next challenge was determining mechanisms for identifying regulatory needs. The Working Group discussed several options which included surveys of NRC and Agreement State material programs and focused discussions at stakeholder meetings. In June 2003, as a test to the pilot, the Working Group decided to request input from NRC and both Agreement and non-Agreement States to identify regulatory needs. This task presented the Working Group with yet another challenge. The Working Group received only 50 percent participation from the stakeholders involved, including one non-Agreement State. To increase stakeholder participation, State representatives on the Working Group encouraged participation via RADRAP electronic list server, telephone calls, and by extending the deadline for input.

As a result of increased participation, the Working Group received a lengthy list of regulatory needs. The Working Group had several discussions on how to reduce the list. Some of the items identified were currently being addressed by collaborative NRC and Agreement State working groups. Therefore, the Working Group decided to exclude those regulatory needs. The group also decided to combine similar items to avoid redundancy. After addressing the challenges, the Working Group successfully developed a comprehensive list to be prioritized.

- **Prioritization Worksheet and Evaluation**

The Working Group developed a worksheet, Attachment 1, to prioritize the regulatory needs identified by NRC and Agreement States. The worksheet was sent to the directors of NRC headquarters and regional materials offices, and all Agreement State radiation control program directors. Initially, there was a low amount of participation in the completion of the worksheets. However, at the annual OAS meeting held in October 2003, the Working Group participated in a session on the NMP, where the worksheet was explained and discussed, in detail, with the Agreement States. In addition, the Agreement States were provided with the opportunity to complete the worksheets at the meeting. As a result, the level of participation increased to 80 percent.

The comprehensive list of Agreement State and NRC regulatory needs was itemized in the worksheet. For every regulatory need listed in the worksheet, the respondents were requested to assign a level of priority to the need as it would contribute to three performance goals: protection of public health and safety, security of radioactive materials, and efficiency and effectiveness. The levels of priority that could be assigned were high, medium, low, and not applicable, as defined by the following:

- high - the regulatory need identified is necessary to achieve, reestablish, or redefine the specific performance goal;
- medium - the regulatory need identified will improve or enhance the specific performance goal;
- low - the regulatory need is expected to have little to no impact on the specific performance goal;
- not applicable - the regulatory need identified is not relevant to the specific performance goal.

The completed worksheets were submitted to the Working Group for analysis, based on a strategy developed by the Working Group. The strategy, described in Attachment 2, was formed through research on statistical methods used in mathematics and review of the NMSS methodology for ranking performance goals. The Working Group also consulted with a statistician, during the development of the strategy.

To enable mathematical analysis of the data, the Working Group converted the levels of priority to numerical values of 3, 2, 1, and 0, respectively. The regulatory needs were first analyzed based on overall level of priority without consideration of their respective contribution to a specific performance goal. The resulting list based on overall need is found in Attachment 3.

The regulatory needs were then analyzed based upon the level of priority assigned to the individual performance goals. The totals from this analysis were then divided into thirds. The resulting priority matrix of regulatory needs is shown in Attachment 4. Finally, based on the matrix and the NMSS methodology, the Working Group developed a prioritized list of regulatory needs, Attachment 5.

In order to validate whether the prioritized list of regulatory needs accurately reflected both NRC and Agreement States needs, the Working Group developed and compared three lists, which included a collective NRC and Agreement State top ten list of prioritized regulatory needs, and two separate top ten lists of prioritized regulatory needs for both NRC and the Agreement States. The analysis showed that NRC and Agreement State needs were very similar. In fact, eight of the top ten needs identified in the three prioritized lists were identical. The Working Group recognized that some needs are unique to certain regulatory jurisdictions, but overall the needs were very consistent. In addition, the Working Group compared results in Attachments 3 and 5, the list of prioritized regulatory needs based solely on numerical values, with no consideration of the contribution to specific performance goals, and the list of prioritized regulatory needs based on the priority matrix, with consideration given to performance goals. This analysis showed that seven of the top ten regulatory needs, on each of the lists, were identical.

- **Framework**

The Working Group examined processes that NRC and Agreement States could use to make decisions on implementing plans for materials program work and how that work could be shared by both entities. A proposed framework was developed, which outlines the structure and process whereby NRC and Agreement States establish priorities and make decisions on cooperative regulatory efforts. The Working Group used the recommendations from the NMP Working Group to develop the process. Under this proposed framework, the NRC and States share responsibility for the identification of regulatory products, prioritization of regulatory needs, and development of corresponding rules, guidance and policy. The proposed framework and process for establishing NMP priorities is contained in Attachment 6, including the function and structure of groups within the Alliance.

The groups involved in the process and their respective functions include:

- A Priorities Committee to develop and provide recommendations to address regulatory needs of the NMP

- A Steering Committee to provide management oversight and make decisions on NRC and Agreement State cooperative regulatory efforts
- An Administrative Core to provide logistical and administrative support for the activities of the NMP

The Priorities Committee is a small group of five or six staff members from Agreement States and NRC, appointed by NRC Office Directors and the Board of Directors of the OAS and the CRCPD. Terms of membership on the Committee should be at least two years to develop consistency and should be staggered to help ensure stability and transfer of knowledge. The Committee will convene twice annually for a prioritization process meeting and will communicate via teleconference and electronic mail as needed.

The Priorities Committee would operate as a clearinghouse for regulatory needs identified by Agreement States and NRC and would periodically analyze identified needs as well as address rapidly emerging regulatory issues and new technologies. The Steering Committee would then make decisions on which, and by whom, regulatory needs would be developed, based on the recommendations of the Priorities Committee, the Centers of Expertise for that particular issue, the availability of staff to participate, a regulatory agency's statutory jurisdiction to regulate the particular issue, and other considerations.

The administrative component of the NMP, the Administrative Core, would assist in the planning of meetings; maintain an information infrastructure for reports, notes, and data; provide logistical support for meetings; and track assignments and products. Initially, the function of the Administrative Core would be undertaken by STP. This office currently tracks and coordinates the activities of joint NRC and State working groups, funds State staff travel, and provides staff support to assist in the compilation of reports and data. Since the CRCPD has an established office for administrative support for State regulatory activities, it is possible that some, or all, of the Administrative Core function could, at some time in the future, be assumed by that office.

The Working Group tested the framework and prioritization process, which included making recommendations on prioritized regulatory needs. During the test, the Pilot Project One Working Group acted as the Priorities Committee, selected NRC managers and the chairs of the CRCPD and the OAS acted as the Steering Committee, and STP acted as the Administrative Core. A teleconference between the Priorities and Steering Committees was conducted. During the teleconference, information on the prioritization process and framework was presented and discussed. The Working Group also presented a list of the top prioritized regulatory needs. In addition, the Working Group presented recommendations on two specific regulatory needs, of which one was a high priority under the performance goal of Protection of Public Health and Safety and the other was a high priority under Security of Radioactive Materials.

The recommendations included the following information:

- the regulatory product needed;
- background information on the regulatory need;
- identification of the organization/working group/individual that should to develop the product;

- resources needed and a potential source(s) of funding (or resources).

The Steering Committee discussed the two recommendations and made consensus decisions on each of them, with little to no modifications. Attachment 7 contains the recommendations on the two high priority regulatory needs. Suggested changes made by the Steering Committee during the teleconference were incorporated in the recommendations.

- **Success Measures**

Pilot Project One only involved the development of a process and framework that NRC and Agreement States could use to establish priorities. Therefore, the majority of the success measures outlined in SECY 02-0074, which relate to the overall success of the NMP under the Alliance Option, do not specifically apply.

1. *Provide insights into whether an informal coalition of State programs and NRC, as envisioned under the Alliance Option, is viable and can produce products meeting needs of both NRC and the Agreement States.*

Although Pilot Project One is not considered an informal coalition, the group demonstrated that such a coalition is viable and can produce products that can be used by both NRC and Agreement States. It is anticipated through the proposed framework that Agreement States and NRC could form ad hoc coalitions, using centers of expertise or existing working groups, to produce specific work products meeting the needs of all parties. The Working Group acted as the Priorities Committee in the proposed framework and developed a prioritized list of regulatory needs. The Working Group, composed of both NRC and Agreement State representatives, demonstrated that it could produce a product meeting the needs of both NRC and Agreement States by developing a process to establish priorities. The use of a Steering Committee for decision making was tested and demonstrated that joint NRC and Agreement State decision making can also be successful. However, further testing would need to be conducted to determine if the commitment of resources by NRC and Agreement States would be successful to produce work products.

2. *Provide insights that the Alliance Option has the potential to be a sustainable program structure for the NMP which will result in fewer NRC resources being needed for the development of products needed by NRC and the Agreement States.*

The scope of this pilot project does not permit the direct demonstration of this success measure. However, the commitment and willingness demonstrated by the Steering Committee in making decisions on regulatory needs showed that the Alliance Option has potential for the more efficient use of resources from both NRC and Agreement States as resources are shared in the development of regulatory products.

3. *Provide demonstration that States can assume and carry out greater responsibility for the development and maintenance of products under a NMP.*

The scope of this pilot project does not permit the direct demonstration of this success measure. However, one of the recommendations made to the Steering Committee

involved the use of two existing CRCPD committees and the funding available to those committees to develop products. This demonstrated the willingness of States to assume greater responsibility for NMP products.

4. *Provide greater assurance that individual State programs are willing and able to commit resources, and to produce products on a schedule that can be utilized by NRC and the Agreement States.*

The Working Group consisted of two State representatives, one of whom is a manager in the Texas Department of Health and the other is the Radiation Control Program Director for the Massachusetts Department of Public Health. Although their positions in the State programs were demanding of their time and efforts, both representatives were able to contribute greatly to the work products developed during the course of the pilot project. In addition, one representative was able to participate as the Co-Chair of the pilot, which required additional responsibilities to that of a working group member. During the course of the pilot, both representatives also used personal time to complete work products, travel, and review documents associated with the pilot project. The Working Group believes that, based on the contributions of the State representatives, State programs are willing and able to commit resources and produce products that can be utilized by both NRC and Agreement States.

5. *Provide insights into whether the NRC will be able in the future to realize resource savings and efficiency gains through shifting of work to States under an Alliance structure.*

The two recommendations that were researched and presented during the test of the proposed prioritization process were work products to be developed with Agreement States having lead responsibility. Although not tested, the Working Group believes the NRC would potentially be able to realize resource savings and efficiency gains by having the Agreement States assume greater responsibility in the development of shared work products.

6. *Provide demonstration that NRC can operate in a NMP framework and will be able to use products which may have been developed by a single State or group of States without the need for major change.*

During the teleconference between the Priorities and Steering Committees, consensus decisions were reached on the two priority recommendations. The NRC managers that participated on the Steering Committee expressed a willingness to participate in the NMP framework and prioritization process developed by the Working Group. As stated in success measure #5, the two recommendations presented and subsequent actions approved were both to be led by Agreement States. The NRC managers had no objections to the lead organizations of the recommendations and felt that the NRC would be able to use the work products, if developed. However, a full test that NRC would be able to use products developed by the Agreement States, without need for major change, was not possible under the scope and definition of this pilot project.

7. *Provide demonstration that NRC is willing to share with the States the establishment of priorities for the NMP including rule and guidance work needed to support the materials and waste arenas.*

This pilot project demonstrated that NRC and Agreement State can collaborate in establishment of priorities and the development of a national priority list. During the course of the pilot project, the Working Group ensured that State needs were known and considered along with those identified by the NRC. In addition, the NRC manager with lead responsibility of the pilot project encouraged Agreement State participation in work product development and in gathering stakeholder input. The Working Group believes that the NRC is willing to share with the States the establishment of priorities and the development of work products for the NMP. The framework and prioritization process developed by the Working Group has outlined how decisions for implementing plans for materials program work could be shared by NRC and Agreement States.

8. *Provide insights to help understand the degree to which Agreement States are aligned with NRC Policy direction to use a risk informed and performance based regulatory approach.*

The scope of this pilot project does not permit the direct demonstration of this success measure.

- **Conclusion**

The Working Group was able to develop a prioritized list of radioactive material program needs at the national level and develop a framework acceptable to both the Agreement States and NRC. However, the activities and work products produced by the Working Group was not able to demonstrate that the Alliance Option is feasible. Further evaluation, such as the implementation of the proposed framework and prioritization process, and an assurance that resources will be committed and allocated for the NMP, is needed to fully determine the feasibility of the Alliance Option.

Time did not permit the Working Group to test the implementation of the proposed framework, whereby assignments are made and work products are produced. Based on past working group involvement by the OAS and CRCPD, the Working Group does not anticipate that there would be any major impediments to the successful establishment of an Administrative Core, Priorities Committee, or Steering Committee. The Working Group believes that the framework can serve the needs of the NMP under the Alliance Option and result in productive sharing of information and resources between Agreement States and NRC.

During the development of the process and framework to jointly establish priorities in a future NMP, the Working Group made the following observations:

- Regulatory needs solicited in the future should provide more information as to the types of needs to be identified. In particular, agency representatives would be encouraged to identify the specific rule, regulation, document, etc., that needs to be developed or changed to address a specific problem. This will assist in defining the regulatory needs for a NMP.

- In developing the comprehensive list of regulatory needs, the Working Group excluded regulatory needs that were currently being addressed by existing working groups. There was the assumption that if a working group was already addressing a regulatory need, the problem would be resolved and was already a high priority. During the discussion of lessons learned from the activities of the pilot project, the Working Group determined that Agreement States could have been included, for involvement or collaboration, on existing working groups for some of the regulatory needs that were excluded. In addition, the Working Group determined that some of the regulatory needs that were identified and eliminated were not being actively pursued due to resources and higher priority items. A national priorities list should include all regulatory needs, whether or not they are currently being addressed. In addition, the group that prioritizes regulatory needs in the future should determine if the working groups addressing identified regulatory needs could further involve or collaborate with Agreement States, and are active, before the item is excluded from the list of regulatory needs.
- The respondents to the prioritization worksheets experienced problems in completing the worksheets. A large majority of the State respondents stated that the performance goals were unclear. Instructions to the worksheet should have included a clear definition of the performance goals.
- Although the functions of each of the groups within the Alliance have been defined broadly, the specifics of the roles and responsibilities of these committees need to be clearly defined, as well as the makeup. Some Agreement States have voiced the sentiment that the Priorities Committee should consist of at least equal representation of Agreement State and NRC staff.
- The involvement of the NRC and Agreement State management earlier in the activities of the pilot project may have facilitated the development of the proposed framework. Specifically, it would have been more reflective of the actual framework and would have facilitated additional interaction and discussions. In addition, it would have given the Working Group the opportunity to gather input on the role and operating procedures of the Steering Committee. Overall, NRC and Agreement State management will need to assume a greater role in a NMP under the Alliance.
- A number of the high priority regulatory needs became projects taken on by OAS, CRCPD, NRC, or individual State organizations. This was due to the turnaround time of the work products developed under the pilot project being artificially long, almost one and a half years. The proposed framework and process, which includes the collection of regulatory needs and the development of recommendations to the Steering Committee would be done twice yearly. It is the intent of the proposed prioritization process and framework developed by the Working Group that subsequent actions relative to the recommendations on prioritized regulatory needs would commence once a consensus is reached by the Steering Committee.
- To aid in the timeliness of the prioritization process, the worksheet and regulatory needs submission process should be a web-based system with results tabulated automatically into a data base. The results could then be easily manipulated into a spreadsheet format. This would allow the Priorities Committee more time to analyze the results,

rather than spending additional time converting individual NRC office and Agreement State responses into an aggregate response.

### **RECOMMENDATION**

The Working Group recommends that, as a first step, NRC and Agreement States (1) accept the Alliance concept, not the full Alliance Option, whereby both parties collaborate in the identification of shared regulatory needs and the production of regulatory work products, and (2) agree to continue to operate under the Blended Option for the National Materials Program.

As a second step, NRC and Agreement States (1) develop operating procedures for the administrative core, Priorities Committee, and Steering Committee, as outlined in the proposed framework, which would include the process for committing resources and ensuring that funds are allocated, and (2) develop an implementation plan for the proposed framework and prioritization process developed by the Working Group.

Finally, NRC and Agreement States (1) establish an administrative core, Priorities Committee, and Steering Committee, (2) implement the prioritization process and framework, and (3) continue to refine the prioritization process as the NMP evolves.

## ATTACHMENT 1

### PRIORITIZATION WORKSHEET

A comprehensive list of NRC and Agreement State regulatory needs were itemized for prioritization. For every regulatory need listed, the respondents assigned a level of priority (high, medium or low) in relation to the three performance goals: 1) protection of public health and safety, 2) security of radioactive materials, and 3) efficiency and effectiveness.

#### **Instructions for Completing the Prioritization of Regulatory Needs Worksheet**

Listed in the left-hand column are regulatory needs that have been identified by NRC and the States. On the right side of the worksheet are the three main performance goals of the States' Radiation Control Programs and NRC's Material Area. **For every regulatory need listed, please assign a level of priority** as it relates to each of the three performance goals. The different levels of priority are: high (H), medium (M), low (L), and not applicable (N/A).

The levels of priority are defined as the following:

- High: The regulatory need identified is necessary to achieve, reestablish, or redefine an adequate amount of the specific performance goal.
- Medium: The regulatory need identified will improve or enhance a specific performance goal. It also indicates that an adequate amount of the specific performance goal is maintained without the regulatory need.
- Low: The regulatory need identified is expected to have little to no impact on the specific performance goal.
- Not Applicable: The regulatory need identified is not relevant to the specific performance goal or your materials program.

**Example:**

State and NRC Regulatory Needs	Performance Goals		
	Protection of Public Health and Safety	Security of Radioactive Materials	Efficiency and Effectiveness
<i>Rulemaking for security of portable gauges.</i>	<i>M</i>	<i>H</i>	<i>M</i>
<i>Resolution of jurisdictional issues for source material.</i>	<i>M</i>	<i>N/A</i>	<i>L</i>
<i>Revision of brochure, "Case Histories of Radiography Events"</i>	<i>L</i>	<i>L</i>	<i>L</i>

**PRIORITIZATION OF REGULATORY NEEDS WORKSHEET**

<b>State and NRC Regulatory Needs</b>	<b>Performance Goals</b>		
	<b>Protection of Public Health and Safety</b>	<b>Security of Radioactive Materials</b>	<b>Efficiency and Effectiveness</b>
<b><i>Source Security</i></b>			
Security review of general licensed device program			
Resolution to collection & disposal/storage of orphaned sources			
Guidance for first responders equipped with radiation monitors			
Role of state radiation control programs in homeland security			
<b><i>Medical</i></b>			
Low Level Waste Disposal rule on medical waste			
Guidance for licensing and inspection of new medical technologies, including medical devices and procedures			
Policy on when “new modality” is no longer “new”			
Update to material guidance on gamma stereotactic radio-surgery units			
Guidance for veterinary medicine treatments involving radioactive materials and release of animals			
<b><i>Disposal Issues/Exemptions</i></b>			
Low Level Waste Disposal rule on NORM contaminated scrap metal			
Low Level Waste Disposal rule on exempt quantities			

<b>State and NRC Regulatory Needs</b>	<b>Performance Goals</b>		
	<b>Protection of Public Health and Safety</b>	<b>Security of Radioactive Materials</b>	<b>Efficiency and Effectiveness</b>
Rulemaking on licensing radioactive mixed waste in the Resources Conservation and Recovery Act			
Rule-making on americium, neutron sources, and large activity source disposal			
Revision to Policy Directive PG 8-10: Disposal of Incineration Ash as Ordinary Waste			
Rules for the disposal of medical waste at refuse facilities, wastewater sludge, and disposal of large quantities of exempt items (e.g., smoke detectors) from the general public or business use			
<b><i>Decommissioning/Financial Assurance</i></b>			
Financial assurance for decommissioning, funding of accidents, disposition of orphaned material, and small industries going bankrupt			
Revision to 10 CFR 30 Appendix B to tie those quantities to calculations for determining financial assurance			
Consensus standards on decommissioning			
<b><i>Industrial</i></b>			
Guidance for the manufacture and distribution of chemical and biological agent detectors			
<b><i>Source Material</i></b>			
Guidance for source material licensing			
<b><i>Licensing and Inspection- Other</i></b>			
Revision of 10 CFR Part 30 to require all Sealed Sources and Devices (SS&D) to have a SS&D Certificate for distribution and usage			
Revision of NUREG 1556, Volume 20 to include standard license conditions			

<b>State and NRC Regulatory Needs</b>	<b>Performance Goals</b>		
	<b>Protection of Public Health and Safety</b>	<b>Security of Radioactive Materials</b>	<b>Efficiency and Effectiveness</b>
Rulemaking on transfers of certain source materials by specific licensees			
Information Technology solution to web-based licensing for the byproduct materials program			
<b><i>Training/Communication/IMPEP/Coordination/Compatibility</i></b>			
Communications system for informing NRC and the States of current issues being developed, including guidance documents, rule developments, and new technologies			
Interactive multimedia training accessible to both NRC and the States			
Identify/develop subject matter experts and technical assistance personnel useful in cases of emergencies			
Guidance on parallel development of the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs), with changes to NRC's regulations, including a process by which SSRs are kept up to date with changes that affect multiple CFR chapters and are compatible with CFRs			
Process to expand the Integrated Materials Performance Evaluation Program (IMPEP) to include NRC Headquarters' material activities			
Develop/host Topical Seminars in areas such as pool irradiators, medical therapy devices, financial sureties, decommissioning, automation of RAM programs and sealed source and device evaluations			
Revision of non-common performance indicators under IMPEP to include review criteria for Sealed Sources and Devices; Low Level Waste; Uranium Recovery; Fuel Cycle; and Site Decommissioning Management Plan			

<b>State and NRC Regulatory Needs</b>	<b>Performance Goals</b>		
	<b>Protection of Public Health and Safety</b>	<b>Security of Radioactive Materials</b>	<b>Efficiency and Effectiveness</b>
Rulemaking on compatibility with IAEA Transportation Safety Standards (TS-R-1) and other Transportation Safety amendments			
<b><i>Public Monitoring/Dose Estimates</i></b>			
Guidance on public monitoring, such as the adoption or endorsement of the Federal Emergency Management Agency's guidance on nuclear power plant incidents			
Update old dose-conversion factors embedded in 10 CFR 20			

## **ATTACHMENT 2**

### **STRATEGY TO ANALYZE WORKSHEETS**

The strategy for analyzing the prioritization worksheet was based on the level of priority assigned to each regulatory need in relation to the three performance goals. The levels of priority were given numerical values and the results were tabulated under each regulatory need.

### **Strategy for Analyzing the Prioritization Worksheets**

1. 33 Completed worksheets were submitted. (25 from Agreement States; 4 from NRC HQ Offices of NMSS, NSIR, STP, and RES; 4 from NRC Regional DNMS offices)
2. The levels of priority were given numerical values as the following:
  - High = 3
  - Medium = 2
  - Low = 1
  - Not Applicable = 0
3. The numerical value of the results from each worksheet were inserted into an Excel spreadsheet. The spreadsheet was set up so that the results are entered under each performance goal, as a table under every regulatory need.
 

*For Example:* If **Regulatory Need A** was identified in the worksheet as High in the *Protection of public health and safety*, Low in *Security of radioactive materials*, and Medium in *Efficiency and Effectiveness*, it would be inserted into the spreadsheet as the following:

<b>Regulatory Need A</b>		
Protection of Public Health and Safety	Security of Radioactive Materials	Efficiency and Effectiveness
3	1	2

4. For every regulatory need, each column of numbers under each performance goal (representing input from worksheet), was then summed. This provided the highest performance goal in which the regulatory need was rated. In addition, the sums of the performance goals were also summed. This provided an analysis on the overall rating for every regulatory need.
 

*For Example:* The spreadsheet would look like the following where **Regulatory Need A** was deemed highest for the protection of public health and safety:

<b>Regulatory Need A</b>		
Protection of Public Health and Safety	Security of Radioactive Materials	Efficiency and Effectiveness
3	1	2
2	0	2
Sum: 5	Sum: 1	Sum: 4
Sum: 10		



**ATTACHMENT 3**  
**OVERALL NEED LIST**

A prioritized list of NRC and Agreement State regulatory needs was developed based on overall level of priority without consideration of the performance goals. This list was used to validate the prioritized list of regulatory needs.

**Prioritized Regulatory Needs based on Overall Need**

<b><u>Total Points</u></b>	<b><u>Regulatory Need</u></b>
1. 229	Resolution to the collection and disposal of orphaned sources
2. 213	Identity of roles of State Radiation Control Programs in Homeland Security
3. 207	Rulemaking on americium, neutron sources, and large activity source disposal
4. 202	Financial assurance for decommissioning, funding of accidents, disposition of orphaned material, and small industries going bankrupt
5. 198	Identify or develop subject matter experts and technical assistance personnel that would be useful in cases of emergencies
6. 187	Develop licensing and inspection guidance for new medical technologies.
7. 186	Security review of general licensed device program
8. 186	Develop and host topical seminars in areas such as pool irradiators, medical therapy devices, etc.
9. 176	Develop a communications system where NRC and the States are informed of current issues being developed
10. 173	Revision of 10 CFR 30 to require all SS&Ds to have a certificate for distribution and usage
11. 171	Develop interactive multimedia training that is accessible to both NRC and the States
12. 171	Develop guidance on parallel development of the Conference of Radiation Control Program Directors Suggested State Regulations
13. 166	Guidance for first responders who will be equipped with radiation monitors
14. 166	Rules for disposal of medical waste at refuse facilities, wastewater sludge, and large quantities of exempt items from the general public or business use
<b><u>Total Points</u></b>	<b><u>Regulatory Need</u></b>

15.	162	Rulemaking on compatibility with IAEA Transportation Safety Standards (TS-R-1) and other transportation safety amendments
16.	159	Develop guidance for veterinary medicine treatments involving radioactive materials and release of animals
17.	156	Updated material guidance on gamma stereotactic radiosurgery units
18.	154	Consensus standards on decommissioning
19.	153	Rulemaking on transfers of certain source materials by specific licensees
20.	153	Revise NUREG 1556, Vol. 20, to include standard license conditions included in all the other volumes of NUREG 1556
21.	148	Rulemaking on licensing radioactive mixed waste in the Resources Conservation and Recovery Act
22.	144	Develop guidance for source material licensing
23.	143	Codified estimates of doses to be received by the public during performance assessments
24.	140	Low level waste disposal rule on NORM contaminated scrap metal
25.	138	Revision of 10 CFR 30 Appendix B to tie those quantities to calculations for determining financial assurance
26.	130	Low level waste disposal rule on exempt quantities
27.	127	Guidance on public monitoring
28.	127	Information technology solution to web-based licensing for the byproduct materials program
29.	125	Develop a process to expand the Integrated Material Performance Evaluation Program (IMPEP) to include NRC Headquarters' material activities
30.	123	Develop guidance for the manufacture and distribution of chemical and biological agent detectors
31.	122	Low level waste disposal rule on medical waste
32.	120	Policy when a "new modality" is no longer "new"

**Total Points****Regulatory Need**

33. 119 Revise non-common performance indicators under IMPEP to include review criteria for sealed sources and devices, low level waste, uranium recovery, fuel cycle, etc.
34. 116 Revision of Policy Directive PG 8-10: *Disposal of Incineration Ash as Ordinary Waste*

*Note: For those regulatory needs whose total points were equal, the regulatory need that valued higher in safety was placed first. When the regulatory needs scored equally in safety, then the need that valued higher in security was placed first.*

**ATTACHMENT 4**  
**PRIORITY MATRIX**

A matrix was developed using the regulatory need key (itemized list of regulatory needs). Based on the three performance goals, each regulatory need was placed under the performance goal in which it scored the highest. A range of scores were generated for each performance goal. The resulting ranges were divided into thirds (top third, middle third, and bottom third) resulting in a priority matrix.

**Priority Matrix of Regulatory Needs based on Performance Goals**

	TOP THIRD	MIDDLE THIRD	BOTTOM THIRD
<b>SAFETY</b>			
C D E F H I L P Q S T U AA GG HH	F D P	AA C HH I H U	L Q T GG S E
<b>SECURITY</b>			
A B M W	B A M		W
<b>EFFICIENCY &amp; EFFECTIVENESS</b>			
G J K N O R V X Y Z BB CC DD EE FF	BB Y	Z DD R O	FF J V X K CC G N EE

**REGULATORY NEED KEY**

- A. Security review of general licensed device program
- B. Resolution to the collection and disposal/storage of orphaned sources
- C. Guidance for first responders who will be equipped with radiation monitors
- D. Identity of roles of state radiation control programs in homeland security
- E. Low Level Waste Disposal rule on medical waste
- F. Develop licensing and inspection guidance for new medical technologies, including medical devices and procedures. (e.g., Y-90 therapy microspheres, procedure for Gliasite treatments with I-125 filled balloons, new isotopes using monoclonal antibodies techniques, non-coronary application for IVB, and Sr/Rb generators)
- G. Policy on when “new modality” is no longer “new”
- H. Updated material guidance on gamma stereotactic radio-surgery units
- I. Develop guidance for veterinary medicine treatments involving radioactive materials and release of animals
- J. Low Level Waste Disposal rule on NORM contaminated scrap metal
- K. Low Level Waste Disposal rule on exempt quantities
- L. Rule-making on licensing radioactive mixed waste in the Resources Conservation and Recovery Act
- M. Rule-making on Americium, Neutron sources, and large activity source disposal
- N. Revision of Policy Directive PG 8-10: Disposal of Incineration Ash as Ordinary Waste
- O. Rules for the disposal of medical waste at refuse facilities, wastewater sludge, and disposal of large quantities of exempt items (e.g., smoke detectors) from the general public or business use

- P. Financial assurance for decommissioning, funding of accidents, disposition of orphaned material, and small industries going bankrupt
- Q. Revision of 10 CFR 30 Appendix B to tie those quantities to calculations for determining financial assurance
- R. Consensus standards on decommissioning
- S. Develop guidance for the manufacture and distribution of chemical and biological agent detectors
- T. Develop guidance for Source Material licensing
- U. Revision of 10 CFR Part 30 to require that all Sealed Sources and Devices (SS&D) containing AEA material have a SS&D Certificate in order to be distributed and used. Currently, generally licensed devices do not require a SS&D Certificate
- V. Revise NUREG 1556, Volume 20, "Guidance About Administrative Licensing Procedures" to include standard license conditions included in all the other volumes of NUREG 1556
- W. Rule-making on transfers of certain source materials by specific licensees
- X. Information Technology solution to web-based licensing for the byproduct materials program
- Y. Develop a communications system where all NRC and the States are informed of current issues being developed, including guidance documents, rule developments, and new technologies
- Z. Develop interactive multimedia training that is accessible to both NRC and the States
- AA. Identify or develop subject matter experts and technical assistance personnel that would be useful in cases of emergencies
- BB. Develop guidance on parallel development of the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs), with changes to NRC's regulations, including a process by which SSRs are kept up to date with changes that affect multiple CFR chapters and are compatible with CFRs
- CC. Develop a process to expand the Integrated Materials Performance Evaluation Program (IMPEP) to include NRC headquarters' material activities
- DD. Develop and host Topical Seminars in areas such as Pool Irradiators, Medical Therapy Devices, Financial Sureties, Decommissioning, Automation of RAM Programs and Sealed Source and Device Evaluations
- EE. Revise non-common performance indicators under IMPEP to include review criteria for Sealed Sources and Devices; Low Level Waste; Uranium Recovery; Fuel Cycle; and Site Decommissioning Management Plan sites
- FF. Rule-making on compatibility with IAEA Transportation Safety Standards (TS-R-1) and other Transportation Safety Amendments
- GG. Guidance on public monitoring, such as the adoption or endorsement of the Federal Emergency Management Agency's guidance nuclear power plant incidents
- HH. Codified estimates, not overly conservative, of doses to be received by the public during performance assessments. In particular, an update to old dose-conversion factors embedded in 10 CFR 20

## **ATTACHMENT 5**

### **PRIORITIZED LIST OF REGULATORY NEEDS**

A prioritized list of regulatory needs was developed using the priority matrix as described in Attachment 4. That is, the performance goals were ranked based on a system which considers the top third of protection of public health and safety as the highest of the performance goals, followed by the top third of security of radioactive materials, etc. The bottom third of efficiency and effectiveness is considered the lowest of all the performance goals.

**Prioritized List of Regulatory Needs based on the following system:**

- I. Protection of Public Health and Safety - Top Third**
- II. Security of Radioactive Materials - Top Third**
- III. Protection of Public Health and Safety - Middle Third**
- IV. Efficiency and Effectiveness - Top Third**
- V. Security of Radioactive Materials - Middle Third**
- VI. Protection of Public Health and Safety - Bottom Third**
- VII. Efficiency and Effectiveness - Middle Third**
- VIII. Security of Radioactive Materials - Bottom Third**
- IX. Efficiency and Effectiveness - Bottom Third**

**Protection of Public Health and Safety - Top Third**

- 1. Develop licensing and inspection guidance for new medical technologies, including medical devices and procedures. (e.g., Y-90 therapy microspheres, procedure for Gliasite treatments with I-125 filled balloons, new isotopes using monoclonal antibodies techniques, non-coronary application for IVB, and Sr/Rb generators) (F)
- 2. Identity of roles of state radiation control programs in homeland security (D)
- 3. Financial assurance for decommissioning, funding of accidents, disposition of orphaned material, and small industries going bankrupt (P)

**Security of Radioactive Materials - Top Third**

- 4. Resolution to the collection and disposal/storage of orphaned sources (B)
- 5. Security review of general licensed device program (A)
- 6. Rulemaking on americium, neutron sources, and large activity source disposal (M)

**Protection of Public Health and Safety - Middle Third**

- 7. Identify or develop subject matter experts and technical assistance personnel that would be useful in cases of emergencies (AA)
- 8. Guidance for first responders who will be equipped with radiation monitors (C)
- 9. Codified estimates, not overly conservative, of doses to be received by the public during performance assessments. In particular, an update to old dose-conversion factors embedded in 10 CFR 20 (HH)
- 10. Develop guidance for veterinary medicine treatments involving radioactive materials and release of animals (I)
- 11. Updated material guidance on gamma stereotactic radio-surgery units (H)

12. Revision of 10 CFR Part 30 to require that all Sealed Sources and Devices (SS&D) containing AEA material have a SS&D Certificate in order to be distributed and used. Currently, generally licensed devices do not require a SS&D Certificate (U)

**Efficiency and Effectiveness - Top Third**

13. Develop guidance on parallel development of the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs), with changes to NRC's regulations, including a process by which SSRs are kept up to date with changes that affect multiple CFR chapters and are compatible with CFRs (BB)
14. Develop a communications system where all NRC and the States are informed of current issues being developed, including guidance documents, rule developments, and new technologies (Y)

**Security of Radioactive Materials - Middle Third**

NONE

**Protection of Public Health and Safety - Bottom Third**

15. Rulemaking on licensing radioactive mixed waste in the Resources Conservation and Recovery Act (L)
16. Revision of 10 CFR 30 Appendix B to tie those quantities to calculations for determining financial assurance (Q)
17. Develop guidance for source material licensing (T)
18. Guidance on public monitoring, such as the adoption or endorsement of the Federal Emergency Management Agency's guidance nuclear power plant incidents (GG)
19. Develop guidance for the manufacture and distribution of chemical and biological agent detectors (S)
20. Low Level Waste Disposal rule on medical waste (E)

**Efficiency and Effectiveness - Middle Third**

21. Develop interactive multimedia training that is accessible to both NRC and the States (Z)
22. Develop and host topical seminars in areas such as pool irradiators, medical therapy devices, financial sureties, decommissioning, automation of RAM programs and sealed source and device evaluations (DD)
23. Consensus standards on decommissioning (R)

24. Rules for the disposal of medical waste at refuse facilities, wastewater sludge, and disposal of large quantities of exempt items (e.g., smoke detectors) from the general public or business use (O)

#### **Security of Radioactive Materials - Bottom Third**

25. Rulemaking on transfers of certain source materials by specific licensees (W)

#### **Efficiency and Effectiveness - Bottom Third**

26. Rulemaking on compatibility with IAEA Transportation Safety Standards (TS-R-1) and other transportation safety amendments (FF)
27. Low Level Waste Disposal rule on NORM contaminated scrap metal (J)
28. Revise NUREG 1556, Volume 20, *Guidance About Administrative Licensing Procedures* to include standard license conditions included in all the other volumes of NUREG 1556 (V)
29. Information technology solution to web-based licensing for the byproduct materials program (X)
30. Low Level Waste Disposal rule on exempt quantities (K)
31. Develop a process to expand the Integrated Materials Performance Evaluation Program (IMPEP) to include NRC headquarters' material activities (CC)
32. Policy on when "new modality" is no longer "new" (G)
33. Revision of Policy Directive PG 8-10: *Disposal of Incineration Ash as Ordinary Waste* (N)
34. Revise non-common performance indicators under IMPEP to include review criteria for sealed sources and devices; low level waste; uranium recovery; fuel cycle; and Site Decommissioning Management Plan sites (EE)

## **ATTACHMENT 6**

### **PROPOSED FRAMEWORK**

A proposed framework was developed describing the structure and process whereby NRC and Agreement States could establish priorities and make decisions on cooperative regulatory efforts. Under the proposed framework, the NRC and Agreement States share responsibility for the identification of regulatory products, prioritization of regulatory needs, and development of corresponding rules, guidance and policy.

### **Proposed Framework for Establishing**

## **National Materials Program Priorities**

***Alliance: A cooperative process between the Agreement States and NRC that identifies radiation safety regulatory priorities and the means to address those priorities.***

### **Function and Structure of Groups within the Alliance:**

- ***The Priorities Committee***

The Priorities Committee develops and provides recommendations to address regulatory needs of the National Materials Program. This committee is made up of representatives of the United States Nuclear Regulatory Commission (NRC) and Agreement States, appointed by NRC Office Directors and the Board of Directors of the Organization of Agreement States, Inc. (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD). Members will serve for identified staggered terms. The Committee will convene twice annually for a prioritization process meeting and communicate via teleconference and electronic mail as needed. The Priorities Committee also acts as a clearinghouse for new priorities that arise in the Agreement States or NRC regulatory programs or that are identified by other stakeholder groups and communicated to the committee.

- ***The Steering Committee***

The Steering Committee provides management oversight of and directs the Alliance process and makes decisions on cooperative Agreement State and NRC regulatory efforts. This committee is made up of NRC Directors of the Offices of State and Tribal Programs (STP), Nuclear Material Safety and Safeguards (NMSS), and Nuclear Security and Incident Response (NSIR); an NRC Regional Division of Nuclear Materials Safety (DNMS) Director; and the chairs of OAS and CRCPD (or their designees).

- ***The Administrative Core***

The Administrative Core provides administrative and logistical support for the National Materials Program, and can be considered the support staff for the Alliance membership. Support includes the tracking of Alliance assignments and products as well as the maintenance of the information infrastructure. Initially, the Administrative core function will be supported by STP. The function may be reassigned to the CRCPD Office of the Executive Director at a future time. No decisions or actions on technical or policy issues related to the established priorities may be made solely by the administrative component of the Alliance; this would negate the consensus nature of the Alliance. The Administrative Core facilitates and enables the Alliance to operate efficiently.

The responsibilities of the administrative core within the Alliance include:

1. Planning, coordination and logistics

The Administrative Core coordinates the logistics of Alliance meetings, whether those meetings are physical or virtual meetings, including arranging for meeting locales and reservations and notification of the arrangements to Alliance members. The Administrative Core could also provide facilitation for these meetings.

2. Tracking Alliance assignments/products

The Administrative Core will maintain documentation of the priorities identified and assignments made by the Steering Committee, including the specific work products, the individuals assigned, and schedules associated with the assignments. The Administrative Core will report any information regarding the assignment to the Steering Committee, who are responsible for evaluating progress and ensuring the quality of products.

### 3. Maintaining Information Infrastructure

An information infrastructure will be established to provide a centralized point for the collection of information, such as regulatory needs, Centers of Expertise, alternative resources, and current successes. Maintenance of the information infrastructure will be provided by the Administrative Core.

### **Prioritization Process:**

1. Regulatory needs are identified to the Administrative Core by the Agreement States and NRC and are communicated to the Priorities Committee. The Agreement States and NRC will consider input from other stakeholders, including licensees, the public, professional organizations, industry organizations, and other Federal and state agencies with an interest in radiation issues. A planning session involving the Steering Committee, Priorities Committee and stakeholders early in the process will give useful insights into technical issues, and other factors that may impact the prioritization process.
2. The Priorities Committee analyzes the identified regulatory needs by determining if the need is currently being addressed, can be combined with a previously identified need, or can be addressed at the next prioritization process meeting. The Priorities Committee develops and maintains a database of regulatory needs.

NOTE: If an issue is determined to be urgent, the Priorities Committee will research the issue and make a recommendation to the Steering Committee regarding its priority and disposition.

3. The Priorities Committee seeks input annually from Agreement States and NRC on the level of priority for identified regulatory needs to be addressed at the next prioritization process meeting. Mechanisms for providing input to the Priorities Committee may include: surveys of the materials programs of NRC Offices and Agreement States and focused discussions at annual OAS, CRCPD, or special called meetings.
4. The Priorities Committee numerically evaluates the input to create a prioritized list of the regulatory needs. The Committee then researches the top priorities to make recommendations to the Steering Committee. The Priorities Committee will address each of the top regulatory needs individually and agree upon the most appropriate course of action. Possible actions include: (1) recommending that a working group be formed to address the priority, including the organization that will have lead responsibility for the group; (2) that the priority has been fully handled through existing products and that these products merely need to be shared with various stakeholders; (3) that no action is necessary; (4) that NRC address the priority; or (5) that an Agreement State

address the priority. Regulatory needs that are not found to be top regulatory needs would be re-prioritized at the next prioritization process meeting.

The Priority Committee will reach a consensus position on the recommended course of action for each regulatory need. If a consensus cannot be reached, several courses of action can be recommended. A vote would be taken and a simple majority would then decide which position would be the preferred option. If additional clarification on a specific regulatory need is necessary before a decision can be reached, the Priorities Committee will further research the topic. Regulatory needs for which both NRC and Agreement States do not have authority will be addressed by the individual organization responsible.

5. A Priorities Committee Recommendation form will be used by the Priorities Committee to present recommendations on the top priorities to the Steering Committee. The form will provide information to assist the Steering Committee in making decisions on implementing plans for work to address specific regulatory needs, including:
  - a. Definition of Regulatory Need – A brief description of the need, including the necessity to address the need, specific information on the scope of the need, and the resources necessary to fully address the specific issue.
  - b. Centers of Expertise and Alternate Resources – The Priorities Committee will examine options for the most efficient and effective method of developing the appropriate work product. The most up-to-date knowledge and experience involving a particular use of radioactive material or regulatory issue may not lie within any one Federal or state agency. Staff from one or more state programs and NRC or other Federal agencies may be identified as having expertise in the designated topic, including those agencies that may have already addressed the need through legislation, rulemaking, guidance or policy. Another center of expertise may be an existing working group within the CRCPD or OAS that has both state and Federal members or resource personnel. Current successes by individual agencies, whether individual state or Federal, in addressing the particular regulatory issue will also be identified as an option for the efficient development of a work product. In addition, alternate resources, such as consensus standards developed by national or international radiation professional organizations, or the involvement or particular professional organizations, may also be included in the recommendations.
  - c. Work Products to be Developed – Specifics on the document(s) to be developed (e.g., draft rules, licensing/inspection guidance, state/Federal policy)
  - d. Estimate of Staff Resources, Travel, and/or Other Expenses – In recommending proposed actions to the Steering Committee, the Priorities Committee will provide an estimate of the FTE commitment needed to develop the specific work products by Agreement State and NRC personnel, as well as the level of involvement of the Administrative Core, since the Administrative Core will track the projects and may provide further logistical support for working groups. If travel and other expenses are anticipated for the project, the cost estimate for those items will be delineated.

- e. Other recommendations as appropriate.
6. The Steering Committee determines what priorities will be worked on, defines specific work products, and determines by whom the product will be developed, with consideration given to budget and other resource requirements (e.g. NRC's Planning, Budgeting, and Performance Management process). The Steering Committee will reach a consensus position on the course of action for each recommended priority. The Steering Committee will use information from their individual budget processes to make decisions and reach consensus on recommendations. If a consensus is not apparent: (1) a vote can be taken and a simple majority would then decide the Steering Committee's position; or (2) if one or more members of the Steering Committee request additional information before deciding upon a course of action, the Steering Committee can delay their decision and request that additional information be gathered by the Priorities Committee.

The Steering Committee will address each priority individually and decide the most appropriate course of action. Possible actions include: (1) directing that a working group be formed to address the priority, including the organization that will have lead responsibility for the group; (2) that the priority has been fully handled through existing products and that these products merely need to be shared with various stakeholders; (3) that additional information is needed before a decision can be reached; (4) that no action is necessary; (5) that NRC address the priority; or (6) an Agreement State address the priority. If the Steering Committee decides that no action is needed for a particular priority, the Steering Committee will note the justification behind the decision, and direct whether the priority will be re-addressed by the Priorities Committee during their next prioritization process meeting.

The Priorities Committee and Steering Committee may hold joint meetings or teleconferences to identify and further define the work products needed and discuss ways each of the work products can be developed most efficiently and effectively with the budgetary and staff resources, and time constraints of all affected agencies and organizations.

7. Decisions of the Steering Committee are communicated to the Priorities Committee by the Administrative Core. Once projects are determined and the resources are committed, the Administrative Core works with the project leaders and tracks the progress of work product development. The lead organization, NRC office, or Agreement State responsible for developing specific work products is also responsible for ensuring that schedules are met. The Steering Committee utilizes input from the Administrative Core to evaluate progress and ensure the quality of final products.

Working groups assigned work products by the Steering Committee may consist of varying combinations of state and NRC staff, other centers of expertise, and/or other resource members, depending on the issue and product to be developed. Working groups will follow the approved guidance in NRC Management Directive 5.3, *NRC/Agreement State Working Groups*, as applicable. Items assigned to working groups led by CRCPD, OAS, or other organization will follow guidance developed by the individual organizations. Final products should receive legal review by NRC's Office of General Counsel.

**ATTACHMENT 7**

**PRIORITIES COMMITTEE RECOMMENDATIONS ON TWO REGULATORY NEEDS**

Two of the highly ranked prioritized regulatory needs were selected to test the framework and prioritization process. The Priorities Committee provided background information on the specific regulatory needs, and made recommendations to the Steering Committee for informed decision-making on work products needed for both the NRC and Agreement States.

**PRIORITIES COMMITTEE RECOMMENDATION**

<b>DATE</b> 7/16/2004	<b>REGULATORY NEED</b> Develop licensing and inspection guidance for the following medical technologies: (1) Y-90 therapy microspheres - Manual brachytherapy sources used for permanent brachytherapy implantation therapy;  (2) Procedure for Gliasite treatments with I-125 filled balloons -Manual liquid brachytherapy sources used for temporary brachytherapy implantation therapy in the Proxima Therapeutic's Gliasite Radiotherapy system;  (3) New isotopes using monoclonal antibodies techniques - Radioactive isotopes attached to monoclonal antibodies used for targeted therapy;  (4) Non-coronary applications for Intravascular Brachytherapy - Intravascular brachytherapy used in applications not involving the coronary vessels of the heart;  (5) Sr/Rb generators - A device that generates and delivers Rb-82 for cardiovascular nuclear medicine procedures.
<b>RANK 1</b>	
<b>PERFORMANCE GOAL</b> Protection of Public Health and Safety	
<b>BACKGROUND</b>  (1) NRC currently has existing licensing and inspection guidance for Y-90 therapy microspheres. The licensing guidance was last revised on February 26, 2004 and the inspection procedures were last revised on October 24, 2002. These documents may be found on the NRC website. The program applicability of these procedures fall under IMC 2800, which was recently revised under National Materials Program Pilot Project Five.  (2) NRC currently has existing licensing and inspection guidance for the procedure for Gliasite treatments with I-125 filled balloons. The licensing guidance was last revised on February 26, 2004 and the inspection procedures were last revised on October 24, 2002. These documents can be found on the NRC website. The program applicability of these procedures fall under IMC 2800, which was recently revised under National Materials Program Pilot Project Five.  (3) New isotopes using monoclonal antibodies is classified as a drug according to 10 CFR 32.72 or equivalent Agreement State requirements. The requirements for licensing this drug are found in 10 CFR Part 35, Sections A, B, and C, and Subpart E. To date, additional guidance has not been needed by the medical licensing community. The inspection procedures were last revised on October 24, 2002, and can be found on the NRC website. The program applicability of these procedures fall under IMC 2800, which was recently revised under National Materials Program Pilot Project Five.  (4) NRC currently has existing licensing and inspection guidance for Intravascular Brachytherapy systems. The licensing guidance does not restrict licensees to only coronary applications. The guidance is written generally to encompass coronary as well as non-coronary applications. The licensing guidance was last revised on May 21, 2004, and the inspection procedures were last revised on October 24, 2002. These documents can be found on the NRC website. The program applicability of these procedures fall under IMC 2800, which was recently revised under National Materials Program Pilot Project Five.  (5) The Sr/Rb generator contains <i>accelerator produced</i> Sr-82 that generates Rb-82, which is not under the jurisdiction of NRC authority. This item was an oversight in the Priorities Committees' process by which those regulatory needs involving material not regulated by both NRC and Agreement States were eliminated from the list of regulatory needs to be prioritized. However, the State of Florida currently has existing licensing and inspection guidance for Sr/Rb generators.	

**PROPOSED ACTION**

- *Option A*

No additional guidance should be developed and no additional actions are needed to supplement the recently revised licensing and inspection guidance, developed by NRC, for the following medical technologies: Y-90 therapy microspheres, Gliasite treatments with I-125 filled balloons, and non-coronary application for intravascular brachytherapy. Also, no additional guidance should be developed and no additional actions are needed to supplement the existing licensing requirements for new isotopes using monoclonal antibodies techniques. As a proposed action, an All Agreement State letter should be developed, by the Administrative Core, to communicate the existing licensing guidance and inspection procedures. The Sr/Rb generator guidance, developed by Florida, should also be communicated to the Agreement States.

- *Option B*

A proposed action is to provide the Agreement States with the opportunity to review the existing licensing and inspection guidance for medical technologies to determine if they are adequate for use in Agreement State radiation control programs. The medical technologies include: Y-90 therapy microspheres, Gliasite treatments with I-125 filled balloons, non-coronary application for intravascular brachytherapy, and new isotopes using monoclonal antibodies techniques. An All Agreement State letter should be developed, by the Administrative Core, to communicate the existing guidance to the Agreement States for review and comment. A working group should be established to evaluate the comments and determine if the guidance is adequate. This working group would be chaired by an Agreement State representative, and consist of three members, representing both NRC and Agreement States. If any of the existing guidance is determined to be inadequate, then the working group should revise the guidance accordingly. If the guidance is deemed adequate, then no additional actions are needed.

**CENTERS OF EXPERTISE**

- *Option A*

Not Applicable

- *Option B*

The working group that is established to revise the guidance should consist of members with experience in writing medical licensing and inspection guidance. Agreement State representatives should have performed or supervised the sealed source and device reviews for the medical technologies. NRC representatives should have expertise in the specific medical technologies. An NRC expert is Donna Beth Howe, NRC/NMSS/IMNS.

**ESTIMATED RESOURCES**

- *Option A*

Not Applicable

- *Option B*

The amount of resources estimated are 80 hours *per working group member*, which includes 25 hours to evaluate comments, 35 hours to research and draft the guidance, and up to 20 hours to finalize the draft.

**STEERING COMMITTEE DECISION**

*Option A.* In addition to Option A, the All Agreement State letter should seek comments on the existing licensing and inspection procedures.

<b>PRIORITIES COMMITTEE RECOMMENDATION</b>	
<b>DATE</b> 7/16/2004	<b>REGULATORY NEED</b>  Resolution to the Collection and Disposition of Orphan Sources, to include guidance for:
<b>RANK</b> 4	1) Development of long-term cost recovery mechanisms for disposal of orphan radioactive material; and  2) Collection and disposal and/or storage of orphan sources and unwanted radioactive material
<b>PERFORMANCE GOAL</b> Security of Radioactive Material	
<b>BACKGROUND</b>	
<p>CRCPD, NRC, EPA, and DOE have each been working on the resolution to the collection and disposition of orphaned sources. However, the national program for dispositioning these sources is in need of greater consolidation. NRC handles emergency requests for disposing of orphan and unwanted sources, in particular AEC sources through the Off-Site Recovery Program (OSRP) and under a Memorandum of Understanding (MOU) with DOE for specific requests. The OSRP is DOE's routine program for collection and disposition of orphan sources. The MOU is for specific requests by NRC for emergency recoveries. CRCPD provides information to assist States and NRC in source dispositioning (lists of waste brokers, individuals who want sources and those that want to get rid of them).</p> <p>For the long term, regulatory agencies need to plan for other funding of orphan source disposition. Several states have legislation in place and have developed rules to address the financial aspects of this issue. Funding at the Federal level may be decreased in the future and may no longer be available to the extent it is now. Some states have passed legislation that would provide for a special fund, made up of surcharges to licensees and/or funds from administrative penalties, to provide for emergency removal, accident or orphan source situations.</p> <p>In the interim, state and federal programs, as well as some licensees (such as waste brokers) need clear, understandable guidance and a list of resources for dispositioning of orphan sources and material. The OSRP has done, and continues to do a good job with Greater than Class C sources, but a similar program is needed for other sources. The national program is somewhat fragmented as only the states that enter into contracts have a funding program for dispositioning. If a revised program can be packaged properly, DOE and other federal agencies would likely be willing to work with the states in completing this mission, which would be a win/win for the states and the federal agencies.</p> <p>In order to achieve some uniformity and clear communication in the form of guidance to the state and federal agencies, the current CRCPD Coordinator for Unwanted Radioactive Material is planning to request a meeting of the CRCPD E-34 advisors (representatives from the appropriate federal agencies) in the fall of 2004 to share information and formulate a plan on enhancing joint efforts.</p>	

**PROPOSED ACTION**

1) To address the issue on long-term cost recovery mechanisms, an additional charge should be added to the CRCPD Suggested State Regulations Working Group on Financial Security (SR-S) to develop model legislation and regulations for funding mechanisms for disposal of orphan sources and other abandoned radioactive material. This work should be coordinated with the E-34 Committee.

(2) To address the issue on the collection and disposal and/or storage of orphan sources and unwanted radioactive material in the near term, a working group, led by the CRCPD E-34 Committee and Coordinator, should be established to develop guidance for a nationwide dispositioning program for orphan sources in coordination with EPA, NRC, and DOE. This guidance should be in the form of a brochure which defines an orphan source and details the various mechanisms and resources available for disposal of orphan sources by NRC and Agreement States.

**CENTERS OF EXPERTISE**

- 1) CRCPD E-34 Committee: Joe Klinger (IL), Coordinator and Chair, and identified resource individuals from NRC, EPA, DOE, LANL, and ORNL  
Department of Energy: Andy Tompkins, Contractor with Los Alamos  
NRC: Michelle Burgess  
CRCPD OED: Terry Devine
- 2) CRCPD SSR Working Group on Financial Security (Item 2 only)

**ESTIMATED RESOURCES**

The amount of resources estimated are approximately 250 person-hours for addressing cost recovery mechanisms and 400 hours total person-hours (80 hours per person) to produce the guidance document, and associated travel expenses for two interface meetings (one meeting of each working group). Potential sources of funding include the CRCPD's FDA umbrella grant for development of model legislation and regulations, and funding from DOE, along with funds from CRCPD's umbrella grant, for production of the brochure.

**STEERING COMMITTEE DECISION**

Proceed with proposed actions