

# POLICY ISSUE NOTATION VOTE

November 13, 2004

SECY-04-0215

FOR: The Commissioners

FROM: Luis A. Reyes  
Executive Director for Operations

SUBJECT: FINAL REPORT ON RESULTS OF THE NATIONAL MATERIALS  
PROGRAM PILOT PROJECTS

## PURPOSE:

1. To respond to Staff Requirements Memorandum (SRM) SECY-02-0107, "Addendum to SECY-02-0074 - National Materials Program: Pilot Projects," dated August 20, 2002.
2. To inform the Commission of the results of the five pilot projects in response to SRM SECY-02-0107.
3. To respond to SRM M030123B, "Briefing on Status of Nuclear Materials Safety and Safeguards Programs - Materials Safety," dated February 13, 2003.
4. To request Commission consideration and approval of future National Materials Program activities.

## SUMMARY:

By SRM dated August 20, 2002, the Commission approved implementation of a blending of the "Current Program" and the "Alliance" options (the Blended option) through the initiation of five pilot projects. Staff provided a status report, SECY-04-0059, "Progress Report for the National Materials Program (NMP) Pilot Projects," to the Commission on April 9, 2004. Each pilot

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project has completed its final report. This paper provides the Commission with staff's assessment of the five pilot projects, stakeholders' feedback (i.e., feedback from representatives from professional organizations, industry, States, and the public), lessons learned from U. S. Nuclear Regulatory Commission (NRC) and Agreement States interactions on materials security issues, and Agreement State resource issues. The Agreement State resource issues concern whether NRC's strategy of having a cooperative enterprise with Agreement States where they would take a portion of work load is still valid given the State's resource constraints.

The pilot projects and interactions between NRC and Agreement States on materials security issues have demonstrated that a coalition of NRC and Agreement State staff can work cooperatively to develop regulatory products under the Blended option. However, to move the NMP to a structure closer to the Alliance option, a set of implementing procedures under this option would need to be developed, and greater assurance of funding at the State level to support Agreement State involvement in the NMP would need to be identified and put in place.

With respect to State resources, staff continues to believe that the strategy of using State experience, expertise and resources remains valid. However, uncertainty associated with the ability of Agreement States to officially budget and commit resources to support NMP activities remains. With respect to stakeholders' feedback, stakeholders expressed the view that the mission, purpose, and goals of the NMP should be made clearer and that the NMP should develop and implement a risk-informed, performance-based regulatory approach for materials safety and waste disposal activities, similar to that currently used by the NRC. Stakeholders also commented on the need for a formal process to get their input early in the development of regulatory priorities.

Based on the assessment, staff has developed options for future NMP activities and a recommendation. Staff recommends that NRC, the Organization of Agreement States, Inc. (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD) continue to function under the Blended option (Option 1). Under the Blended option, staff believes that the NMP will continue to evolve as new opportunities for collaborative work are identified and implemented without the need for additional resources. Follow-on work and assessment of recommendations in the individual pilot project working group reports can serve as a basis for possible future collaborative work.

#### BACKGROUND:

SRM SECY-02-0107 approved implementation of a blending of the Current Program and the Alliance options through the initiation of five pilot projects. The Current Program<sup>1</sup> represents the NMP that existed when SECY-02-0107 was finalized. The Alliance option<sup>2</sup> represents a possible future evolved state of the NMP where NRC and Agreement States would work cooperatively to identify, prioritize, and address the regulatory needs (including schedule and

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<sup>1</sup> The Current Program is discussed on pages 3.6-3.15 in the Final Report of the NMP Working Group (SECY-01-0112-Attachment 1, ML011590431).

<sup>2</sup> The Alliance Option is discussed on pages 3.30-3.44 in the Final Report of the NMP Working Group (SECY-01-0112-Attachment 1, ML011590431).

resources) of the materials program. It was also envisioned that NRC would have the authority to regulate discrete Naturally Occurring and Accelerator-Produced Radioactive Material (NARM), which NRC currently does not regulate.

The Blended option, represents an NMP structure which essentially reflects how NRC and Agreement States interact and operate today as an NMP. NRC and Agreement States work cooperatively and look for opportunities to increase use of State experience, expertise, and resources in the development and maintenance of regulatory products such as rules and guidance documents. SECY-04-0059 provides background on previous actions relating to the NMP and pilot projects.

The full NMP Pilot Project Implementation Plan was provided as Attachment 1 of SECY-04-0059. Attachment 1 of this paper provides an update of the Implementation Plan's Milestones and Schedule.

During the pilot project activities, the Office of State and Tribal Programs (STP) and the Office of Nuclear Material Safety and Safeguards (NMSS) Directors, and the OAS and CRCPD Chairs provided collective management oversight.

#### DISCUSSION:

##### 1. Evaluation of Pilot Project Results

Each pilot project working group report contains recommendations for consideration by NRC and Agreement States, and analyses against the success measures provided in SECY-02-0074. The pilot project final reports are available in the Agencywide Document Access and Management System (ADAMS, ML 043100337). The pilot project activities are summarized in Attachment 2. A summary of each pilot project working group response to the success measures is contained in Attachment 3.

The pilot projects and experiences from NRC and Agreement States activities to enhance materials security demonstrated that NRC, Agreement States, and the States' two representative organizations (OAS and CRCPD), can work cooperatively to develop regulatory products. The pilot projects also demonstrated the commitment and ability of OAS, CRCPD, and individual Agreement States to identify and provide staff to the working groups. However, additional assessment will be needed to determine whether specific recommendations and work products of the pilot projects will be used and implemented by NRC and Agreement States. (See last paragraph of each pilot project summary contained in Attachment 2.) Also, the pilot projects did not provide information on how individual Agreement States budget and account for resources devoted to NRC and Agreement State working group activities.

Agreement State and NRC staff participation in some working groups was affected by competing work priorities in the staff members' home organization or by the need to participate in planned internal staff developmental activities. In some cases, work on the NMP pilot projects was performed as an activity added to the existing licensing, inspection, or regulatory development work of the pilot project participants. Staff recognizes that the success of the pilot projects was partially due to the enthusiasm and dedication of the individual pilot project participants.

The level of effort devoted by STP to overall project management of the pilot projects was greater than initially expected. Project management activities required additional work by individual pilot project Chairs. For example, additional effort was required to prepare an overall implementation plan and schedule, participate in monthly status calls, and provide periodic status reports to STP.

NRC staff and the OAS and CRCPD Chairs believe the two single most significant uncertainties identified from the pilot project experience, and which relate to future implementation of the NMP are: 1) assurance of availability of Agreement State staff resources to support continuation of joint NMP activities; and 2) the ability and willingness of NRC to share decision making with the Agreement States on setting priorities, how work products will be developed, and on the content of work products.

Based on the pilot project results, the following two areas would need to be addressed to move the NMP closer to the Alliance option:

- (a) Assurance of budgeted funding to support Agreement States' involvement in NMP activities.

Although Agreement States have been actively involved in a full range of NMP activities, such as participation in working groups and in the Integrated Materials Performance Evaluation Program, individual Agreement States do not currently have the ability to budget resources explicitly for NMP activities. State radiation control program budgets authorize expenditure of State resources dedicated to support State activities. Consequently, the resources needed to support the NMP activities are not explicitly included in State budgets. The CRCPD has funded the development of regulatory products for use by State programs through its budget and staff resources provided by individual State programs and CRCPD staff. An example includes development of the Suggested State Regulations.

During the panel discussion of the NMP at the September 2004 OAS annual meeting, the OAS Chair asked the State program directors about the ability of State radiation control programs to budget resources earmarked to support NMP activities. A number of program directors responded that it would not be possible to explicitly fund NMP activities in State budgets. Some program directors stated that they could potentially provide matching State funds if Federal funds were provided to the States under grants to support NMP activities. Thus, it is unclear whether a coalition, as envisioned under the Alliance option, dependent on State resources which are not formally budgeted or committed to support NMP activities could be sustained for a long period of time, or have assurance that needed regulatory products could be effectively and efficiently developed, when needed.

In SRM M030123B, a question was raised concerning whether the strategy of having a cooperative enterprise with Agreement States where they would take a portion of work load is still valid given the State's resource constraints. The results of the pilot projects indicate that individual Agreement States are able to identify and assign State staff resources to support NMP activities, including States experiencing resource constraints. However, uncertainty associated with the ability of Agreement States to budget and commit resources to support NMP activities remains.

NRC's budget commits resources to support its involvement in NMP activities. These resources are included in budget categories related to support of materials regulatory development activities. Resources, both full time equivalent (FTE) and funding, are also included to support NRC and Agreement State working group activities.

Due to the uncertainty associated with the ability of Agreement States to officially commit resources to support NMP activities, staff does not believe the Commission can adopt the Alliance option without assurance of adequate and sustained Agreement States funding to support their NMP activities.

- (b) Development of implementing procedures for NMP.
- (i) Development of implementing procedures for defining how needs for new regulatory products would be identified and prioritized jointly by NRC and Agreement States.

The proposed framework (Attachment 4) for establishing NMP priorities was developed by Pilot Project 1. Under the proposed framework, a Priorities Committee would be formed with the responsibility to develop and maintain a repository of regulatory needs and to develop recommendations to address high-priority needs. The Committee would also consider input from stakeholders. A Steering Committee would be established to support the Priorities Committee and to provide oversight and facilitate NRC and Agreement State decisions on cooperative regulatory efforts. An Administrative Core would be established to provide administrative and logistical support.

NRC, OAS and CRCPD would first need to agree to use the Pilot Project 1 prioritization methodology or a modified methodology. Specific implementing procedures would then be developed to address: (1) how the Priorities Committee, Steering Committees, and Administrative Core would operate; (2) how to involve stakeholders early in the process of identifying regulatory needs and priorities; and (3) how the Steering Committee would obtain approval from respective agency management on resource commitments for developing work products (i.e., the Commission through NRC's Planning, Budgeting, and Performance Management [PBPM] process, and State management through individual State resource allocation processes).

- (ii) Development of implementing procedures for defining roles and responsibilities for managing the development of regulatory products.

The experience with the pilot projects points out a need for greater understanding of the roles and responsibilities of the Steering Committee, (i.e., STP and NMSS Directors, and OAS and CRCPD Chairs) and those of management within the organization assigned the lead responsibility for the pilot project or working group. Although the Steering Committee reviewed and approved pilot project Charters and work product plans, it was unclear whether the lead organization should have responsibility for ensuring the success of its assigned working group or whether the Steering Committee as a whole should have that responsibility.

In addition, during the pilot project activities, changes to the milestones and schedule were proposed and finalized by the pilot project Chairs and the STP project manager. In some cases, these changes were reviewed and approved by the STP Director in coordination with the NMSS Director, and the Chairs of OAS and CRCPD. However, there were no implementing

procedures for the Steering Committee to follow in reviewing and approving such changes, and providing guidance and/or making appropriate adjustments to ensure that progress in the quality and timeliness of regulatory products is achieved.

Specific implementing procedures needed include: (1) defining the roles and responsibilities of the Steering Committee and the Administrative Core; and (2) success measures and guidance for the Steering Committee to evaluate progress made by the working groups, to approve schedule changes proposed by the working groups, and to ensure that the product is usable and completed on time.

## 2. Pilot Project Resource Utilization

As stated in SECY-02-0074, specific resource estimates for each pilot project were determined based on development of individual implementation plans for each pilot project. Based on the Charter for each pilot project working group, a total of 6,943 hours was estimated for completion of the five pilot projects, with NRC staff contributing 3,947 hours.

During the period between December 28, 2002, and September 18, 2004, NRC and Agreement State staff worked approximately 6,369 hours on the five pilot projects, with NRC staff contributing 4,165 hours. Of the 6,369 hours, 177 hours were non-regular (overtime) hours. There were 11 State staff members from seven Agreement States participating in the pilot project activities. NRC had 12 staff members who participated: three from STP, five from NMSS, one from Region I, two from Region III, and one from the Office of the Chief Financial Officer. Most of the staff effort supporting Pilot Project 5 was accomplished prior to December 28, 2002, by NRC staff members as part of their normal work in support of the existing Inspection Manual Chapter (IMC) 2800 working group. Therefore, only two staff members (one NRC and one Agreement State) from the Pilot Project 5 are included in the totals above. Pilot project working group members are listed in Attachment 5. A list of estimated vs. actual resources for each individual pilot project is provided as Attachment 6.

## 3. Stakeholders' Feedback

The pilot project working groups and NRC staff sought opportunities to inform stakeholders and receive their feedback on pilot project activities. These activities included publication of Federal Register notices and use of a dedicated NMP page on the NRC web site where NMP related documents such as pilot project Charters, work product plans, and documents for review and comment were made available. NRC and Agreement State staff members made presentations at the annual CRCPD and OAS meetings, the Advisory Committee on Medical Use of Isotopes meetings, and the 2004 Health Physics Society annual meeting.

In addition, staff conducted a stakeholders' meeting on March 31, 2004, to inform stakeholders of the status and progress of the pilot projects and to solicit feedback on the structure and framework of the NMP. Stakeholders included representatives from professional organizations, industry, States, and the public. Stakeholder comments covered a broad spectrum of areas including the organizational structure of the NMP, jurisdiction and policies, program implementation, and future NMP activities.

In general, stakeholders expressed the view that the mission, purpose, and goals of the NMP should be made clearer and that the NMP should develop and implement a risk-informed,

performance-based regulatory approach for materials safety and waste disposal activities, similar to that currently used by the NRC. Stakeholders commented on the need for a formal process to get their input early in the development of regulatory priorities. An open communication process should be developed among NRC, Agreement States and stakeholders to discuss regulatory priorities for the upcoming years and factor the results of the discussion into NRC and Agreement State planning processes. A summary list of stakeholders' comments is provided as Attachment 7. Each pilot project working group considered feedback from the stakeholders' meeting in preparing the final working group report.

#### 4. Lessons Learned from NRC and Agreement States Interactions on Materials Security Issues

On July 2, 2004, STP issued a memorandum to the NRC program offices, OAS, CRCPD, and several working groups and steering committees on materials security issues requesting their input on lessons learned from NRC and Agreements States interactions on materials security that can be applied to the work on the NMP. Overall, staff received positive feedback from NRC and Agreement State staff working on materials security issues. The feedback indicated that development of the additional materials security measures was more resource intensive than initially expected due to issues related to the bases for such measures and that Agreement State staff participation in these activities added significant value in helping shape the content of the additional security measures.

OAS indicated that the Materials Security Working Group (MSWG) has demonstrated the likely success of the Alliance structure by realizing resource savings and efficiency gains for NRC through the partnering relationship between NRC and Agreement States. OAS also indicated that the MSWG experienced challenges in working with NRC management in developing its products and expressed the view that a permanent common defense and security framework is not reflective of a true alliance. Specific lessons learned that can be applied to the NMP are summarized in Attachment 8.

#### 5. Path Forward for the Future NMP

Based on results of the pilot projects, NRC, OAS, and CRCPD staff identified three options for Commission consideration:

- Option 1. Continue to operate the NMP under the Blended option.
- Option 2. Option 2 is the same as Option 1 with the addition of a joint NRC/Agreement State process for prioritizing materials program work and a joint NRC/Agreement State agreement on respective roles and responsibilities for developing major work products.
- Option 3. In addition to activities covered under Option 2, NRC, OAS, and CRCPD would explore possible mechanisms to assure funding of State NMP activities. If State funding was assured, NRC, OAS, and CRCPD would proceed to develop implementing procedures to enable operation of the NMP under the Alliance option.

The options are described in further detail below.

Option 1. Continue to operate the NMP under the Blended option.

Under this option, NRC and the Agreement States would continue to collaboratively address materials issues within the constraints of available resources. Given the additional workload experienced under the pilot projects associated with the functions of the Administrative Core, a formal Administrative Core would not be implemented. Instead, STP would continue to serve as the overall coordinating organization for working groups established by NRC. OAS or CRCPD would serve as the overall coordinating organizations for working groups established by OAS or CRCPD, respectively.

Individual Steering Committees, as provided for under Management Directive 5.3, would be established, as determined to be necessary, to provide management direction and support from NRC, OAS, and CRCPD for specific working groups. Under this option, the relationship between NRC and Agreement States would continue to evolve as Agreement States continue to demonstrate ability to provide State staff resources for the development of NMP products. NRC, OAS and CRCPD would examine recommendations contained in the pilot project working group reports and from stakeholders' feedback as possible areas for future collaborative work within existing budgeted resources.

Pros:

- ! No additional resources would be required.
- ! NMP products would reflect both NRC and Agreement State involvement and thus have greater likelihood of acceptance.
- ! Agreement State experience, expertise, and resources would continue to be applied.
- ! Opportunity to have more experience with Agreement State ability to provide staff resources.

Cons:

- ! NRC would continue to face uncertainty in the ability of Agreement States to budget resources to support NMP activities.

Option 2. Option 2 is the same as Option 1 with the addition of a joint NRC/Agreement State process for prioritizing materials program work and a joint NRC/Agreement State agreement on respective roles and responsibilities for developing major work products.

Under this option, in addition to activities covered under Option 1, a modified version of the prioritization process developed by the Pilot Project 1 working group would be prepared and used by NRC and Agreement States, including procedures for prioritization of materials program work and for stakeholders' involvement. The process would need to be revised to align with NRC's PBPM process. Implementing procedures as stated under Section 1.(b)(i) of the Discussion section, with the exception of those for the Administrative Core, would be developed.

Under this option, the lead organization assigned responsibility to develop a specific product would need to separately determine their ability to devote resources to develop the product based on their internal resource allocation process (e.g., NRC's PBPM process). If approved, the lead organization would also be responsible for tracking and evaluating the progress of each assignment and product development, providing guidance, and making appropriate adjustments to ensure that progress is made.

Pros:

- ! Agreement States would assume a greater role in the prioritization of specific regulatory needs and how these needs would be met.
- ! Most NMP products would reflect NRC and Agreement State input and thus have greater likelihood of acceptance.
- ! Stakeholders' input would be considered in the prioritization process.
- ! Agreement State experience, expertise and resources would continue to be applied.
- ! Opportunity to have more experience with Agreement State ability to provide staff resources.
- ! NRC and Agreement States would share decision making on implementing plans to address specific regulatory needs for which resources are available.
- ! Agreement States would have increased responsibility for State development and maintenance of NMP products.

Cons:

- ! NRC would continue to face uncertainty in the ability of Agreement States to budget resources to support NMP activities.
- ! Additional resources would be required to establish and administer the Priorities and Steering Committees and to support their operation.
- ! Additional efforts would be needed to align the Pilot Project 1 working group product with the NRC's PBPM process.
- ! Decisions on development of specific products would be subject to individual organizational budget processes and reprogramming based on changing needs or priorities.

Option 3. In addition to activities covered under Option 2, NRC, OAS, and CRCPD would explore possible mechanisms to assure funding of State NMP activities. If State funding was assured, NRC, OAS, and CRCPD would proceed to develop

implementing procedures to enable operation of the NMP under the Alliance option.

Under this option, NRC, OAS, and CRCPD would explore possible mechanisms for funding State NMP activities and thereby increase overall State participation in the NMP. If State funding was assured, NRC, OAS, and CRCPD would then develop implementing procedures as stated in Section 1.(b) of the Discussion to enable operation of the NMP under the Alliance option.

Pros:

In addition to the pros under Option 2:

- ! Could lead to identification of a mechanism to fund State activities supporting the NMP, thereby increasing State involvement and potentially reducing NRC resources.
- ! Clear implementing procedures to guide the NMP under the Alliance option would be developed to guide NRC and Agreement State activities resulting in a more equal partnership between NRC and Agreement States in conducting NMP activities.

Con:

- ! Additional resources would be required to examine funding options, to develop implementing procedures, and to support routine operation.

#### RESOURCES:

Resources necessary to continue to implement current NRC staff activities in the NMP (Option 1, the Blended Option) are included in the current FY 05 and 06 budgets. Agreement State resources would continue to be identified and assigned by OAS and CRCPD. NRC and Agreement State resources would need to be included in future respective fiscal year budgets.

Additional NRC resources would be necessary to implement Option 2. They are estimated to be 1.3 FTE (0.1 for OGC, 0.5 for NMSS, and 0.7 for STP) and \$3,000 for STP for travel and per diem over one year to establish procedures for the Priorities and Steering Committees. Additional future resource needs to support routine operation of these Committees are estimated to be 1.3 FTE (0.2 for OGC, 0.6 for NMSS, and 0.5 for STP) and \$6,000 for STP in travel and per diem per fiscal year. Agreement State FTE costs would continue to be identified and assigned as currently handled by OAS and CRCPD.

Additional NRC resources necessary to begin implementation of Option 3 are estimated to be 3.8 FTE (0.3 for OGC, 2.0 for NMSS, and 1.5 for STP), and \$9,000 for STP for travel and per diem. The resources covering activities over one year to examine options for funding of State NMP activities are estimated to be 1.6 FTE (0.1 for OGC, 1.0 for NMSS, and 0.5 for STP), and \$3,000 for STP for travel and per diem and followed by two years to develop implementing procedures to enable operation under the Alliance option. The resources for developing the implementing procedures are estimated to be 2.2 FTE (0.2 for OGC, 1.0 for NMSS, and 1.0 for STP), and \$6,000 for STP for travel and per diem. An estimate of the expected annual fiscal year level of resources would depend on the implementing procedures, the roles and

responsibilities of NRC and Agreement States, the organization selected to perform the Administrative Core function, and the funding mechanism selected. Agreement State FTE costs to support activities to begin implementation of this option would continue to be identified and assigned as currently handled by OAS and CRCPD.

RECOMMENDATION:

Staff recommends that the Commission approve Option 1.

Staff believes that, under this option, NRC and Agreement States, within the constraints of available resources, can continue to work collaboratively and look for opportunities to increase use of Agreement State experience, expertise, and resources. This would effectively use collective resources and allow the NMP to further evolve without the need for additional expenditure of resources to implement Options 2 or 3. Follow-on work including assessment of recommendations in the individual pilot project working group reports and assessment of stakeholders' feedback could serve as a basis for future collaborative work efforts within existing budgeted resources.

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 paper for resource implications and has no objections. This paper has also been coordinated with the OAS and CRCPD Chairs, Past-Chairs, and Chair Elects and they concur in the paper and its recommendation.

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Luis A. Reyes  
Executive Director  
for Operations

Attachments:

1. NMP Pilot Projects Implementation Plan: Milestones and Schedule
2. Summary of Pilot Project Activities
3. Summary of Pilot Project Working Group's Responses to Success Measures
4. Proposed Framework for Establishing National Materials Program Priorities
5. List of Pilot Project Working Group Members
6. List of Estimated vs. Actual Resources
7. Summary of Stakeholders' Comments
8. Summary of Lessons Learned from Collaboration on Materials Security Issues

## Pilot Projects Implementation Plan: Milestones and Schedule

1. Finalize Basic Charters - January 15, 2003 (critical date) (Pilot Project Chairs)  
Status: Completed    Pilot Project 1: 1/29/03  
                                 Pilot Project 2: 1/29/03; revised 3/28/03  
                                 Pilot Project 3: 2/05/03  
                                 Pilot Project 4: 1/29/03  
                                 Pilot Project 5: 1/29/03
2. Send out letter asking NRC Offices, and OAS and CRCPD Chairs for membership on pilot project working groups - January 17, 2003 (NRC/STP)  
Status: Completed 1/29/03
3. Finalize Implementation Plan, using agreement on this schedule and final Charters, including an introduction with Purpose and Background related to all pilot projects - January 23, 2003 (NRC/STP)  
Status: Completed 1/29/03
4. Develop Commission Notation Vote Paper to request extension, in accordance with Implementation Plan, and distribute to Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS and CRCPD Chairs for concurrence - January 27, 2003 (NRC/STP)  
Status: Completed 2/5/03
5. Concurrences on the Commission Notation Vote Paper due - February 7, 2003 (Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS and CRCPD Chairs)  
Status: Completed 4/3/03
6. Incorporate any comments on Commission Notation Vote Paper and submit it to Executive Director for Operations (EDO) - February 14, 2003 (NRC/STP)  
Status: Completed 4/4/03
7. Submit Commission Notation Vote Paper to Commission - February 28, 2003 (NRC/EDO)<sup>1</sup>  
Status: Completed 4/25/03
8. Submit nominations for membership on pilot project working groups to NRC/STP - February 28, 2003 (NRC Offices, OAS and CRCPD Chairs)

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<sup>1</sup>The Notation Vote Paper was replaced by a Memorandum to the Commission.

Status: Pilots 1, 2, 3 and 5 were established with partial or full membership by February 28, 2003, although additional membership changes occurred between March and July. The membership for Pilot 4 was established on January 30, 2004. Note that all Pilots Chairs were selected by spring 2003; the Pilot 4 Chair was replaced in December 2003 due to change of position of the original Chair in the State organization.

9. Hold Monthly progress meetings by conference call

Status: Conference calls have been held on a monthly basis since March 2003.

10. Develop Work Product Plan for Each Charter and submit them with the Basic Charters to NRC/STP, OAS and CRCPD Chairs for concurrence (by April 15, 2003) - March 28, 2003 (Pilot Project Chairs)

Status: Completed    Pilot Project 1: 6/19/03            Pilot Project 2: 4/21/03  
                                 Pilot Project 3: 7/09/03            Pilot Project 4: See item 29  
                                 Pilot Project 5: 6/20/03

11. Publish Federal Register Notice - March 31, 2003 (NRC/STP)

Status: Notice announcing the formation of the pilot project working group was published on 4/23/03.

12. Complete initial update NRC NMP Web site, adding Staff relevant Requirement Memoranda and other documents, and use for obtaining stakeholder feedback, with later updates as appropriate - April 2003 (NRC/STP)

Status: Initial update completed on 4/30/03. The web site is being updated on an on-going basis.

13. Concurrences on Work Product Plans and Revised Charter due - April 15, 2003 (NRC/STP, NRC/NMSS, OAS and CRCPD Chairs)

Status: Pilot Project 1: requested concurrence (Charter and Work Product Plan [WPP]) by 6/19/03; STP: comments received 7/14/03; concurrence received 8/8/03; NMSS: 7/3/03; OAS: 6/23/03; CRCPD: 6/20/03.

Pilot Project 2: requested concurrence (Charter and WPP) by 3/28/03; STP: 8/14/03; NMSS: 4/25/03; OAS: 6/25/03; CRCPD: 3/27/03 (Charter), 4/22/03 (WPP).

Pilot Project 3: requested concurrence (Charter and WPP) by 7/9/03; STP: 7/14/03; NMSS: 7/25/03; OAS: 7/14/03; CRCPD: 7/21/03.

Pilot Project 4: See item 33.

Pilot Project 5: requested concurrence by 6/20/03 (Charter) and by 7/9/03 (WPP); STP: 7/14/03 (Charter & WPP); NMSS: 7/3/03 (Charter), 8/19/03 (WPP); OAS: 6/25/03 (Charter), 7/10/03 (WPP); CRCPD: 6/26/03 (Charter), 7/9/03 (WPP)

14. Brief at CRCPD meeting - May 4-7, 2003 (NRC/STP and Pilot Project Chairs)  
 Status: Completed 5/7/03.
15. Revise Implementation Plan, using agreement on the revised schedule and final Charters - August 25, 2003  
 Status: Completed 8/20/03.
16. Brief at OAS meeting - October 14-17, 2003 (NRC/STP and Pilot Project Chairs)  
 Status: Completed 10/17/03.
17. Progress Report due to STP from Pilot Project Chairs - January 14, 2004  
 Status: Completed    Pilot Project 1: 1/14/04  
                                  Pilot Project 2: 1/14/04  
                                  Pilot Project 3: 1/20/04  
                                  Pilot Project 4: 1/14/04  
                                  Pilot Project 5: 1/14/04
18. Draft Progress Report distributed to Pilot Project Chairs for concurrence - January 23, 2004  
 Status: Completed 1/23/04.
19. Comments due from Pilot Project Chairs on draft Progress Report - January 29, 2004  
 Status: Completed 1/29/04.
20. Complete draft pilot project reports and products, including an analysis against the success measures as set forth in SECY-02-0074 and provide to NRC/STP, NRC/NMSS, OAS and CRCPD Chairs for review - February 2, 2004 (critical date) (Pilot Project Chairs)  
 Status: Pilot Project 1: received on 2/2/04; extended to 9/8/04 due to additional work (see item 40)  
                                  Pilot Project 2: 2/2/2004  
                                  Pilot Project 3: see item 30  
                                  Pilot Project 4: extended to 9/8/04 (see item 40)  
                                  Pilot Project 5: see item 40
21. Distribute Progress Report to NRC: STP, NMSS and OGC; OAS, CRCPD for concurrence - February 18, 2004 (NRC/STP)  
 Status: Completed 2/26/04.
22. Complete review of draft pilot project reports/products prepared by Pilot Project Chairs - March 15, 2004 (NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD)

Status: Pilot Project 1: see item 42  
Pilot Project 2: requested concurrence by 5/16/04; STP: 6/30/04;  
NMSS: ; OGC: 5/13/04; OAS: 6/3/04; CRCPD: 6/3/04.  
Pilot Project 3: see item 31  
Pilot Project 4: see item 42  
Pilot Project 5: see item 42

23. Concurrence on Progress Report due to NRC/STP - March 5, 2004 (NRC: STP, NMSS and OGC; OAS and CRCPD Chairs)

Status: Completed 3/11/04.

24. Submit Progress Report to NRC/EDO - March 17, 2004 (critical date) (NRC/STP)

Status: Completed 3/19/04.

25. Submit Progress Report to the Commission - March 31, 2004 (NRC/EDO)

Status: An extension to April 14, 2004 was approved to provide additional time needed to address and reflect staff comments in the progress report. The report was submitted to the Commission on 4/9/2004.

26. NMP Stakeholders' Meeting - March 31, 2004 (NRC/STP and Pilot Project Chairs)

Status: Completed 3/31/04.

27. Complete final pilot project reports/products and submit copies to the Director, NRC/STP, and OAS and CRCPD Chairs - no later than April 15, 2004 (critical date) (Pilot Project Chairs)

Status: Pilot Project 1: see item 47  
Pilot Project 2: see item 47  
Pilot Project 3: see item 35  
Pilot Project 4: see item 47  
Pilot Project 5: see item 47

28. Brief at CRCPD meeting - May 23-26, 2004 (NRC/STP and Pilot Project Chairs)

Status: An NMP poster was presented at the meeting.

29. Develop Pilot Project 4 Work Product Plan and submit it with the Basic Charter to NRC/STP, NRC/NMSS, OAS and CRCPD for concurrence - May 28, 2004 (Pilot Project 4 Chair)

Status: Completed 5/28/04.

30. Complete draft pilot project 3 reports/products, including an analysis against the success measures as set forth in SECY-02-0074 and provide to NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD Chairs for review - August 9, 2004 (Pilot Project 3 Chair)  
Status: Completed 9/13/04.
31. Complete review of draft pilot project 3 reports/products - August 20, 2004 (NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD)  
Status: Completed STP: 10/12/04; NMSS: 10/6/04.
32. Complete draft report to the Commission and distribute for review by Pilot Project Chairs - June 15, 2004 (NRC/STP)  
Status: Completed 6/21/04.
33. Concurrences on Pilot Project 4 Work Product Plans and Revised Charter due - June 18, 2004 (NRC/STP, NRC/NMSS, OAS and CRCPD)  
Status: STP: 6/18/04; NMSS: 6/17/04; OAS: 6/21/04; CRCPD: 6/29/04.
34. Conference call on draft report - June 23, 2004 (NRC/STP and Pilot Project Chairs)  
Status: Completed 6/23/04.
35. Complete final pilot project 3 reports/products and submit copies to the Director, NRC/STP, OAS and CRCPD Chairs - September 3, 2004 (Pilot Project 3 Chair)  
Status: Completed 10/29/04.
36. Complete first revised draft report to the Commission and distribute for review by Pilot Project Chairs - July 12, 2004 (NRC/STP)  
Status: Completed 7/19/04.
37. Conference call on first revised draft report - July 21, 2004 (NRC/STP, Pilot Project Chairs)  
Status: Completed 7/21/04.
38. Complete second revised draft report to the Commission and distribute for review by Pilot Project Chairs, NRC/STP, NRC/NMSS, NRC/OGC, OAS, and CRCPD - August 16, 2004 (NRC/STP)  
Status: Completed 8/20/04.
39. Conference call on second revised draft report - August 24, 2004 (Pilot Project Chairs, NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD)

Status: Completed 8/24/04.

40. Complete draft pilot projects 1, 4 and 5 reports/products, including an analysis against the success measures as set forth in SECY-02-0074 and provide to NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD for review - September 8, 2004 (Pilot Project 1, 4 and 5 Chairs)

Status: Completed Pilot Project 1: 9/8/04  
Pilot Project 4: 9/10/04  
Pilot Project 5: 9/9/04

41. Complete third revised draft report to the Commission and distribute for review by Pilot Project Chairs, NRC/STP, NRC/NMSS, NRC/OGC, OAS, and CRCPD - September 13, 2004 (NRC/STP)

Status: Completed 9/23/04.

42. Brief at OAS meeting - September 21-24, 2004 (NRC/STP)

Status: Completed 9/24/04.

43. Complete review of draft pilot projects 1, 4 and 5 reports/products - September 22, 2004 (NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD)

Status: Completed OAS: 9/26/04 (pilot 4 draft report only); NMSS: 10/6/04;  
STP: 10/12/04.

44. Conference call on third revised draft report - September 27, 2004 (Pilot Project Chairs, NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD)

Status: Completed 9/27/04.

45. Complete final report to the Commission and distribute for review by Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS, and CRCPD - October 8, 2004 (NRC/STP)

Status: Completed: Final draft sent for review and comment on 10/8/04. Package sent out for concurrence on 10/29/04.

46. Conference call on final report - October 18, 2004 (NRC/STP, Pilot Project Chairs)

Status: Completed 10/18/04.

47. Complete final pilot projects 1, 4 and 5 reports/products and submit copies to the Director, NRC/STP, OAS and CRCPD Chairs - October 29, 2004 (Pilot Projects 1, 4 and 5 Chairs)

Status: Pilot Project 1: 10/29/04  
Pilot Project 4: 11/2/04

Pilot Project 5: 10/21/04

48. Obtain concurrences of Pilot Project Chairs, NRC/STP, NRC/NMSS, NRC/OGC, OAS and CRCPD on final report to the Commission, to NRC/STP Director - October 29, 2004

Status: Completed STP: 10/29/04; OGC: 11/4/04; OAS: 11/4/04; CRCPD: 11/5/04.

49. Submit final report to the Commission - November 12 , 2004 (critical date) (NRC/EDO)

## Summary of Pilot Project Activities

Pilot project Chairs were selected starting in October 2002, pilot project Charters were developed in December 2002 through February 2003, and subsequently a working group was established for each pilot project following Management Directive 5.3. (The Pilot Project 4 working group was established in January 2004. OAS chose not to establish a working group for the Pilot Project 4 until they had identified a new use of material or modality.) NRC and Agreement State staff jointly developed a "NMP Pilot Projects Implementation Plan," including detailed schedules and milestones. The Plan provided a step-by-step guide for implementing the pilot projects, leading to the submission of each individual pilot project final report and the final NMP paper. Once established, each working group developed a pilot project specific work product plan to meet milestones identified in the Implementation Plan.

The lead organization for the Pilot Projects are: Pilot Project 1-STP, Pilot Project 2-CRCPD, Pilot Projects 3 and 5-NMSS, and Pilot Project 4-OAS. The Charter and work product plan for each pilot project were reviewed and approved by the STP and NMSS Directors, and OAS and CRCPD Chairs.

STP provided day-to-day project management support for the pilot projects and carried out the "administrative core" staff functions envisioned under the Alliance option. This included initial drafting of the Implementation Plan; assistance in report drafting; administrative support, when requested by the pilot project Chairs; maintenance of the NMP website; and coordination of activities such as the Federal Register Notices, presentations to the annual CRCPD, OAS and Health Physics Society (HPS) meetings, and stakeholders' meeting.

The STP project manager held monthly conference calls with the pilot project Chairs beginning in March 2003. During the conference calls, pilot project Chairs provided status reports and updates on the progress of the pilot projects. The STP project manager also distributed the conference call meeting notes including pilot project status reports and updates to principal NRC, OAS and CRCPD management and staff (i.e., STP and NMSS Directors, OAS and CRCPD Chairs, pilot project Chairs and working group members).

Changes to the Implementation Plan milestones and schedule were discussed in the monthly pilot project Chairs conference calls and distributed to the STP and NMSS Directors, and OAS and CRCPD Chairs on a regular basis. Pilot project Chairs worked closely with their lead organizations. Joint meetings with the management of other participating organizations were held when needed, to discuss issues and to reach consensus on how individual pilot project issues should be addressed and resolved.

In addition, NRC managers and staff members were invited to provide feedback and input on specific areas including Deputy Director of the Office of the Nuclear Security and Incident Response, the Assistant General Council for Rulemaking and Fuel Cycle of the Office of the General Counsel, the Division Director of the Region I Division of Nuclear Materials Safety, the Branch Chief for Radiation Protection, Environmental Risk and Waste Management Branch of the Office of Nuclear Regulatory Research, and two staff members from the Office of the Chief Financial Officer.

The following is a summary of each pilot project:

### **Pilot Project 1**

Pilot Project 1: Establishment of a prioritization process for development of materials policy, rulemakings, and guidance documents. To meet its objectives, the Pilot Project 1 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 management and the Chairs of OAS and CRCPD (or their designees).

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.

While Pilot Project 1 demonstrated that NRC and Agreement States could work together under a joint process to prioritize materials program work and develop a proposed framework for establishing NMP priorities, additional work is needed to define how commitments of resources to be used for development of work products would be incorporated into NRC and State budget processes such as NRC's Planning, Budgeting, and Performance Management (PBPM) prioritization process.

### **Pilot Project 2**

Pilot Project 2: CRCPD's G-34 Committee on Industrial Radiography serve as the lead organization to oversee a national industrial radiographer safety certification program. Currently, 10 States and the American Society for Nondestructive Testing, Inc. (ASNT) are recognized as certifying entities. Only ASNT has submitted a formal application requesting recognition as a certifying entity; and no formal, follow-up evaluations of any of the existing certification programs have been conducted, underscoring the need for a centralized certification forum. The final work products consist of two documents specifying radiographer certification program evaluation and review criteria. The working group's final report provides recommendations for future NRC activities, including rulemaking, needed to support a national certification system.

The pilot project demonstrated that NRC, States and ASNT could share resources toward the common goals of shaping policy, maintaining a safety perspective, and developing procedures and products that could provide consistency in the certification programs nationwide.

While Pilot Project 2 demonstrated that an existing CRCPD working group can effectively develop criteria for a national radiographer safety certification program, NRC and CRCPD need

to reach agreement on CRCPD implementation of a national radiographer safety certification program.

### **Pilot Project 3**

Pilot Project 3: Operating experience evaluation. This pilot project has examined NRC and Agreement State processes for collecting, reviewing, analyzing, and disseminating lessons learned from operating experience. The working group's final report provides recommendations for improving the communication and consistency of operating experience evaluation between NRC and Agreement States, enhancing integrated decision making through decision-oriented activities, and updating procedures to reflect current needs and government-wide initiatives. The pilot project demonstrated that electronic media can be used effectively to achieve initiatives and partnering between Agreement States and NRC without undue burden of travel. The pilot indicated that a diversity of approaches can be applied to the NMP and recommended that working groups and surveys be pursued on a more selective basis.

While Pilot Project 3 developed a number of specific recommendations on how NRC and Agreement States can better collaborate in the evaluation and use of operational experience and event information, recommendations for enhancing communications, procedures, processes, and for development of a possible operating experience clearinghouse need to be considered by NRC and Agreement States.

### **Pilot Project 4**

Pilot Project 4: States develop licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved. This pilot project working group identified iodine-125 seed localization of non-palpable lesions for guidance development. To meet its objectives, the working group completed the following work products: (1) licensing guidance for use of iodine-125 seed localization for non-palpable lesions, and (2) inspection guidance for iodine-125 seed localization procedures. The pilot project demonstrated that Agreement States can assume the responsibility for development of licensing and inspection guidance for use by both NRC and Agreement States.

While Pilot Project 4 demonstrated that OAS can take the lead to develop licensing and inspection guidance for a new use of material, it is not known at this time whether NRC and Agreement States will use the licensing and inspection guidance developed by Pilot Project 4.

### **Pilot Project 5**

Pilot Project 5: Revision of Inspection Manual Chapter (IMC) 2800, Materials Inspection Program. This pilot project working group completed its tasks in revising the IMC 2800 and seven associated routine inspection procedures for non-medical types of use. The revised materials inspection program is currently being implemented by the NRC Regional offices. The working group queried the Agreement States about implementation of revised IMC 2800 and the inspection procedures. About 20 percent of the States responded. The States which responded indicated that their routine inspections are more frequent than the revised IMC 2800. The pilot project demonstrated that the overall labor rate for routine inspections was reduced in each of the NRC's Regional offices.

While Pilot Project 5 demonstrated that NRC and Agreement States can work cooperatively to draft and pilot test revisions to guidance documents, i.e., the risk-informed and performance based revised IMC 2800 procedures, it is not known at this time whether Agreement States will embrace and implement inspection procedures consistent with the revised IMC 2800 procedures.

## Summary of Pilot Project Working Group's Responses to Success Measures

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.

Development and maintenance of the NMP Pilot Projects Implementation Plan demonstrated that NRC and States can cooperatively work together to achieve a common goal under an NMP.

Pilot Project 1 demonstrated that a coalition of Agreement States and NRC is viable and can produce products that may be used by both NRC and Agreement States. Specifically, Agreement State and NRC can collaborate in establishment of priorities and development of a national priority list. The pilot project working group developed a framework and tested a prioritization process that could be used in the future to establish priorities under the Alliance option.

Pilot Project 2 demonstrated that use of an existing center of expertise (an existing CRCPD committee with knowledge, backgrounds and skills in the radiographer certification area) as envisioned under the Alliance option is an efficient and effective method in developing and applying regulatory products.

Pilot Project 3 demonstrated that work can be accomplished remotely with the use of electronic communications without the need for travel to attend meetings.

Pilot Projects 4 demonstrated that a future NMP under the Alliance option can be a viable NMP structure and can produce regulatory products. The pilot project working group has developed licensing and inspection guidance for use by both NRC and Agreement States.

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.

Pilot Project 2 demonstrated that the Alliance option is the appropriate structure for the NMP. Historically, the radiography safety certification effort has been conducted under what one may consider an "Alliance" of NRC, Agreement States, CRCPD and other industry organizations. The continuation of this project will result in resource savings for all participants. It would cost NRC more to independently develop a similar product. NRC cost would include additional burden of coordinating the final product with the States and radiography community and reconciling differences.

Pilot Project 4 demonstrated that the Alliance option is a sustainable program structure for the NMP. The pilot project was charged to develop licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved by the NRC. The pilot project was implemented by the OAS. The development of guidance which will be used by both the NRC and Agreement States will

result in resource savings for all participants by eliminating duplication of efforts and will provide consistent oversight across the nation.

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

Individual State programs have long been willing and able to commit resources and staff in support of the development of products to be utilized by both the NRC and the Agreement States. Many Agreement State staff have served as members of working groups and writing teams for NUREGs and other technical documents.

State staff's participation in the five pilot projects and completion of the final products by these pilot projects demonstrated that Agreement States can carry out greater responsibility for the development of products needed by NRC and the Agreement States.

Pilot Project 2 demonstrated that States can take a lead role in developing regulatory products to be used in implementing and sustaining today's radiography safety certification program.

Pilot Project 4 demonstrated that States can assume the responsibility for development of licensing and inspection guidance for use by both NRC and Agreement States. The pilot project working group was implemented by the OAS and consisted of four Agreement State members and one NRC member.

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.

Pilot Project 1 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.

Pilot Project 2 was implemented by the CRCPD and its working group consisted of three Agreement State members, two NRC members and one member from the industry. Completion of the pilot project demonstrated that Agreement States are willing and able to commit resources, and to produce products on a schedule that can be utilized by NRC and the Agreement States.

Pilot Projects 3 notes that substantial challenges exist for participation in NRC and Agreement State pilot projects. Pilots and working group activities are often conducted with existing resources, in most cases, as an added activity to the existing work of candidate participants. Individual States will participate in working groups when the issue is important to them, but an adequate level of involvement can be achieved when the solicitation of working group activities and membership are done mutually by the NRC and the Agreement States. The ability of the working group to achieve progress and meet schedules is highly dependent on the staffing and budgeting environment of the sponsoring organization. In general, no work is given up to support pilot and working group activities. Professional development activities also compete, and travel, in support of pilot activities may not be well-supported, even if NRC funding can be arranged via the NMP. States indicated a desire to participate where the initiative addresses concerns that are of mutual interest to them but noted some States may not share the same issue or be able to support projects requiring long-term commitments.

Pilot Project 4 was implemented by the OAS and its working group consisted of four Agreement State members and one NRC member. Completion of the pilot project demonstrated that Agreement States are willing and able to commit resources, and to produce products on a schedule that can be utilized by NRC and the 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.

Pilot Project 1 tested the prioritization process as envisioned under the Alliance option, which included making recommendations on prioritized regulatory needs. During the test, the Pilot Project 1 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, the working group presented recommendations on two specific regulatory needs. The two recommendations were work products to be developed with Agreement States having lead responsibility. The NRC will be able to realize the resource savings and efficiency gains by having the Agreement States assume greater responsibility in the development of shared work products.

Pilot Projects 2 and 4 demonstrated that a center of expertise within the Agreement States as envisioned under the Alliance option was able to develop regulatory products for use by NRC and Agreement States. Since Agreement States share the resources with NRC in developing regulatory products, NRC can realize resource savings under an Alliance structure.

6. Provide demonstration that NRC can operate in an 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.

As stated under success measures #5, Pilot Project 1 noted that 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 Pilot Project 1 working group. 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 expected that the NRC would be able to use the work products, if developed.

Pilot Project 2 indicated that based on NRC's past participation in the development of radiography safety certification concepts, policy development and implementation of a compatible certification program, and acceptance of general industrial radiography certification products, its working group believes that NRC could operate under an NMP as envisioned under the Alliance option.

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.

Pilot Project 1 demonstrated that NRC and Agreement States 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 works products development for the NMP. The framework and prioritization process developed 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.

Pilot Project 3 indicated that the use of risk information has substantial benefit for the allocation of resources for both NRC and Agreement State programs. A challenge is that risk-informed work products need to be packaged to serve end-user needs. States do not have staff's trained explicitly in the use of risk analysis methods. NRC has developed some tools, expertise, and methods for integrating risk into regulatory decision-making. More work is needed to codify these actions into procedures for use in the operating experience program.

## **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 (NMP). This committee is made up of representatives of the United States Nuclear Regulatory Commission (NRC) and Agreement States, appointed by NRC 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 NMP 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 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. 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 organizations will follow guidance developed by the individual organizations. Final products should receive legal review by NRC's Office of General Counsel.

## List of Pilot Project Working Group Members

Pilot Project Number	Working Group Members
Pilot No. 1  Establishment of Priorities	Shawn Smith, NRC/STP (Co-Chair) Ruth McBurney, Texas (Co-Chair) James Lynch, NRC/R III Jayne Halvorson, NRC/NMSS Anita Turner, NRC/NMSS Kimberly Ferrell, NRC/OCFO Robert Walker, Massachusetts
Pilot No. 2  National Industrial Radiographer Certification Program	Jan Endahl, Texas (Chair) J. Bruce Carrico, NRC/NMSS James Myers, NRC/STP Lauren Palmer, Georgia David Turberville, Alabama Donny Dicharry, ASNT/NDTMA
Pilot No. 3  Operating Experience Evaluation	Michael Markley, NRC/NMSS (Co-Chair) Marcia Howard, Ohio (Co-Chair) Duncan White, NRC/RI Debbie Gilley, Florida
Pilot No. 4  State Guidance Development	Robert Gallagher, Massachusetts (Chair) Cassandra Frazier, NRC/RIII Debbie Gilley, Florida Eric Jameson, Georgia Gibb Vinson, Illinois

Pilot Project Number	Working Group Members
Pilot No. 5  Revised Inspection Manual Chapter (IMC) 2800, Materials Inspection Program	<p><i>Writing Team:</i>            Thomas Young, NRC/NMSS (Team Leader and Pilot Chair)</p> <p>Anita Turner, NRC/NMSS            Jim Smith, NRC/NMSS            John McGrath, NRC/RI            John Pelchat, NRC/RII            James Cameron, NRC/RIII            Michael Fuller, NRC/RIV            Richard Blanton, NRC/STP            Robert Gallagher, Massachusetts</p> <p><i>Pink/Red Team (policy direction to Writing Team):</i></p> <p>Thomas Essig, NRC/NMSS            Christiana Lui, NRC/NMSS            George Pangburn, NRC/RI            Gary Shear, NRC/RIII            Elmo Collins, NRC/RIV            Josephine Piccone, NRC/STP            Stuart Treby, NRC/OGC            James Peterson, South Carolina</p>

### List of Estimated vs. Actual Resources

Activities	Actual hours 12/28/02 - 9/18/04	Estimated hours
Overall Project Activities*	1,665 (NRC: 1,358; State: 307)	N/A
Pilot Project 1	1,987 (NRC: 1,584; State: 403)	2,880
Pilot Project 2	1,220 (NRC: 379; State: 841**)	1,348
Pilot Project 3	976 (NRC: 626; State: 350)	1,680
Pilot Project 4	347 (NRC: 56; State: 291)	900
Pilot Project 5***	174 (NRC: 162; State: 12)	135
Total	6,369 (NRC: 4,165; State: 2,204**) (Regular: 6,192, Non-regular hours: 177)	6,943 (NRC: 3,947; State: 2,996)

\* NMP overall project activities included work on implementation plans, Commission paper, progress report, OAS and CRCPD presentations, and participation on monthly pilot project Chairs conference calls. These hours were contributed mainly by pilot project Chairs and the NMP project managers.

\*\* An industry representative who served as advisor to the working group contributed 169 hours.

\*\*\* Most of the staff effort supporting Pilot Project 5 was accomplished prior to December 28, 2002 by staff members as part of their normal work in support of the existing IMC 2800 working group, which is not included in the total hours spent on the pilot project.

## Summary of Stakeholders' Comments

On March 31, 2004, NRC conducted a stakeholders' meeting, open to the public, to inform stakeholders of the status and progress of the pilot projects and receive feedback on the future National Materials Program (NMP). The meeting was transcribed and a copy of the transcription is available at <http://www.hsrdoornl.gov/nrc/materials/0331NRC1397.pdf>. Comments received at the stakeholders' meeting, and those subsequently submitted by letter fell roughly into 4 broad areas:

- Structure/Organization and Infrastructure
- Jurisdiction and Policies
- Implementation/Integration of Current Programs
- Future Issues for Consideration

A more detailed description of the types of comments for each area follows:

### **STRUCTURE/ORGANIZATION AND INFRASTRUCTURE**

- Determine how and when to involve external stakeholders.
- Define the NMP mission, purpose, organizational structure in plain English.
- Evaluate and prioritize regulatory oversight for cross-jurisdictional activities
- Establish NMP short, medium and long term goals.
- Coordinate NMP operations with NRC and State budget preparation activities
- Communicate NMP organization and purpose outside NMP.

### **JURISDICTION AND POLICIES**

- Develop and implement a unified risk informed, performance based regulatory foundation for materials safety and waste disposal.
- Blend OAS, CRCPD, State and Federal programs and practices into a consistent, comprehensive national risk-based program.
- Establish performance measures/metrics to assess program effectiveness.
- Apportion regulation and oversight activities to appropriate regulatory bodies - some issues may be best addressed by the Agreement States, while others are best handled by the NRC, i.e., physical security.
- Increase the sharing of information and tools among affected organizations.
- Develop and communicate common goals and priorities to external stakeholders.
- Solicit and consider external stakeholder input on policy/program development.

### **IMPLEMENTATION/INTEGRATION OF CURRENT PROGRAMS**

- Apply risk informed performance based regulatory principles to more aspects of materials safety.

- Share licensing, operating and inspection experiences among regulators and the regulated community, i.e., lessons learned from State regulatory activities and event notifications.
- Evaluate staff certification/training requirements for appropriate radiation workers (establish a national standard?).

### **FUTURE ISSUES FOR CONSIDERATION**

- Consider sharing resources to address emergent issues.
- Are there other available resources - consider using professional societies.
- How should NMP address physical security issues?
- How best to oversee manufacturing and distribution activities?
- Could an IMPEP-like process be used to assess other types of programs?
- How to handle NORM?
- What about PET in Non-Agreement States?
- Periodically reassess radiation regulations/standards.

## Summary of Lessons Learned From Collaboration on Materials Security Issues

### Lessons Learned Regarding State Collaboration on Materials Security Issues

NRC staff noted that early NRC work on materials security issues (first half of 2002) was carried out without significant Agreement State input. Early State involvement is needed to gain State perspectives, clarity of roles and responsibilities, and resolve State concerns.

OAS expressed the view that materials security efforts have benefitted significantly by the Commission's decision to involve the expertise and perspective of the States in developing security measures. The OAS agrees with the Commission and NRC Staff that involvement of the Agreement States on the Materials Security Working Group (MSWG) and Steering Committee (MSSC) was necessary to develop finely conceived techniques for implementation at the State and local level. The OAS expressed the additional view that the contributions of the Agreement States on MSWG and MSSC was a demonstration that NRC and Agreement States could collaborate effectively from divergent points.

OAS cautions that MSWG and MSSC assistance toward implementation of materials security under common defense and security framework should not be loosely used to prove the viability of the NMP alliance. The OAS notes that for collaborative efforts to be truly reflective of a true alliance, members of the alliance must be able to contribute equitably. Due to Constitutional and statutory limitations on Federal authorities, common defense and security precludes a fully equitable alliance between the NRC and Agreement States. Agreement States can assist only in a supporting role for the common defense and security framework. OAS expresses an additional concern that the provisions of the 274i agreements were balanced more in favor of NRC, and that the agreements should therefore not be loosely used to prove the viability of the NMP alliance.

### Lessons Learned from Working Group Activities

NRC staff noted that Agreement State representatives in working groups have been very helpful in gathering information, conducting surveys, obtaining consensus among States, and acting as a conduit for reporting progress made in working groups to other States. Working group participants should have a clear understanding as to how the working group interacts with the Commission, and with NRC and Agreement State management. Working groups members should be familiar with Management Directive (MD) 5.3, "NRC/Agreement State Working Groups", and MD 3.5, "Attendance at NRC Staff Sponsored Meetings" regarding activities involving predecisional information.

NRC staff further noted that at the initial meetings of all new working groups, MD 5.3 should be discussed, so that all participants clearly understand each other's roles, including and especially, the role of the lead agency, management advisors, and the Steering Committee (if applicable). Working group participants should have a clear understanding of schedules, milestones, personnel involved and their roles and

responsibilities, level of effort expected, decision making process, and NRC and Agreement State issues that affect working group activities.

In addition, the expected final disposition of the working group's product(s) should be discussed, so that it is clear that once a working group product passes from the working group, it is up to the organization for whom the product was developed (usually the lead agency) to determine how the final product is to be used, and that the recipient agency may ultimately reject the product altogether, with appropriate justification.

#### Lessons Learned Regarding Section 274i Inspections

NRC staff noted that NRC could have better predicted the States' equipment needs such as the computers and encryption devices needed by State inspectors, to protect Safeguard Information. In addition, NRC should build more time, i.e., 18 months vs. 12 months, into the schedule for the Section 274i inspection activities initiated to comply with the protective measure Orders, to account for the delays due to the complexities of State government.