

POLICY ISSUE INFORMATION

April 9, 2004

SECY-04-0059

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROGRESS REPORT FOR THE NATIONAL MATERIALS PROGRAM
PILOT PROJECTS

PURPOSE:

To provide a status report on the progress of the National Materials Program (NMP) pilot projects.

BACKGROUND:

In November 1999, the Commission approved the staff plan SECY-99-250, "National Materials Program: Request Approval of the Formation of a Working Group on the Increase in the Number of Agreement States and Impact on NRC'S Materials Program," dated November 14, 1999, to form a working group to address the impacts of the increased number of Agreement States and to provide advice to the NRC on the NMP.

The NMP working group, which included six representatives from States, six NRC representatives and an advisor, completed its final report in May 2001. After evaluating comments from stakeholders, considering the advantages and disadvantages of six structural options for the NMP, and the potential resource implications for each option, the working group provided its final report and recommended that the Commission adopt the Alliance Option (SECY-01-0112, "National Materials Program: Transmittal of the Final Working Group Report Presenting Options for a National Materials Program, dated June 22, 2001). The Alliance Option is a cooperative process between the Agreement States and NRC that identifies radiation safety regulatory priorities and the means to develop national regulatory products in a NMP.

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Subsequently, the NRC staff, and the Organization of Agreement States, Inc. (OAS) and Conference of Radiation Control Program Directors, Inc. (CRCPD) Executive Boards collaborated in the development of five pilot projects that were provided to the Commission in SECY-02-0074, "National Materials Program: Pilot Projects," dated May 3, 2002. The five pilot projects were proposed to provide additional information to help understand the feasibility and viability of the Alliance Option recommended by the NMP working group. SECY-02-0107, an Addendum to SECY-02-0074, was issued on June 18, 2002 to request Commission approval of the staff's and OAS and CRCPD Boards' recommendation for using a blended approach of the Current Program and the Alliance Option. In a Staff Requirements Memorandum (SRM), dated August 20, 2002, the Commission approved implementation of a blending of the Current Program and the Alliance Option through the initiation of five pilot projects.

The five pilot projects are:

- Pilot Project 1: Develop a process that could be utilized by NRC and the Agreement States in the establishment of national priorities for the development of materials policy, rulemaking, and guidance products.
- Pilot Project 2: Assumption by Agreement States/CRCPD of lead responsibility for the oversight of a national radiographer certification program, which includes the review and approval of State government and independent organizations' initial applications to be recognized as certifying entities, review of subsequent program changes, and the responsibility for follow-up evaluations of program activities such as test administration and program maintenance.
- Pilot Project 3: Participation of Agreement States and NRC to optimize the use of operating experience information from licensed facilities and trending in integrated NRC and Agreement State review, assessment, and decision-making processes.
- Pilot Project 4: Assumption by an Agreement State of responsibility for development of licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved.
- Pilot Project 5: Implementation of specific Phase I and II recommendations, and finalize ongoing work to draft and pilot test revisions to Inspection Manual Chapter (IMC) 2800 and routine inspection procedures.

DISCUSSION:

Pilot project chairs were selected in October 2002, pilot project charters were developed in December 2002, and subsequently a working group was established for each pilot project following Management Directive 5.3, except for Pilot Project 4. (Pilot Project 4 was established on January 30, 2004. OAS chose not to establish a working group for 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 (Attachment 1). The Plan provides a step-by-step guide for implementing the pilot projects, leading to the submission of the final report to the Commission in November of 2004. Once established, each working group developed a pilot project specific work product plan to

meet milestones identified in the Implementation Plan. The charter and work product plan for each pilot project were reviewed and approved by the OAS and CRCPD Chairs, and, the NMSS and STP Office Directors.

The lead organization for Pilot Project 1 is the Office of State and Tribal Programs (STP), CRCPD for Pilot Project 2, the Office of Nuclear Material Safety and Safeguards (NMSS) for Pilot Projects 3 and 5, and OAS for Pilot Project 4. During the course of the pilot project activities, pilot project chairs worked closely with their lead organizations. Joint meetings with the leadership of the other organizations were held to reach consensus on individual pilot project issues, as needed. The Executive Boards of OAS and CRCPD, and NRC management have functioned as “regulatory decision makers”¹ as envisioned under the Alliance Option for the pilot projects.

STP also assumed lead responsibility to carry out overall project management and to provide the administrative support² for the pilot projects. The administrative function includes planning, coordination, logistics, tracking assignments and maintaining information infrastructure through a dedicated NMP web site. STP also provided funding for travel and per diem of the State members on the working groups to attend pilot project meetings. In addition, pilot projects have utilized electronic media to send information to both Agreement and non-Agreement States and to coordinate activities of the pilot project representatives.

As of March 6, 2004, NRC and State staff have worked approximately 4,360 hours on the five pilot projects, with NRC staff contributing 2,900 hours. The majority of the hours were spent on Pilot Projects 1, 2 and 3, and overall project management activities. Only a small portion of the total hours were spent on Pilot Project 4. Most of the staff effort supporting Pilot Project 5 was accomplished by staff members as part of their normal work in support of the existing IMC 2800 working group, and is therefore, not included in the total hours spent on the pilot project.

Actions Completed

Attachment 2 provides the status of milestones for each of the working groups’ activities identified in the Pilot Projects Implementation Plan. Attachment 3 provides a status report for each pilot project. A model format for Attachment 3 was provided to the chairs of each pilot project working group. However, the contents of the status reports were individually prepared and submitted by each working group. Except for Pilot Project 4 (due to its late start), each pilot project has met the major milestones identified in its work product plan. Major accomplishments and status for each pilot project are summarized as below:

- Pilot Project 1 working group, led by STP, on the establishment of priorities, examined current processes used by NRC and Agreement States to establish their agencies’ priorities. The working group developed a prioritized list of regulatory needs based on input from Agreement States, and NRC

¹“Regulatory decision makers” are discussed on page 3.37 in the Final Report of the NMP Working Group (SECY-01-0112).

²See “Administrative Core” discussed on pages 3.40-3.41 in the Final Report of the NMP Working Group (SECY-01-0112).

headquarters and regional offices. In parallel with the development of the prioritized list, the working group also developed a proposed framework and process that NRC and the Agreement States could use to prioritize regulatory needs in the NMP under the Alliance Option. Pilot Project 1 is currently in the process of refining and testing its proposed framework and prioritization process to determine if it could be used by NRC and Agreement States to establish priorities and reach decisions on implementing plans for materials program work and to determine how that work would be shared.

- Pilot Project 2 working group, led by CRCPD, on a national industrial radiographer safety certification program, formalized the draft criteria and process for reviewing a new application from a State or an organization seeking recognition as a certifying entity, or for reviewing program changes from existing certifying entities. The working group has also enlisted the participation of a State having an existing certification program to test its revised criteria and process. The working group is in the process of finalizing its pilot project report.
- Pilot Project 3 working group, led by NMSS, on operating experience evaluation, has completed the information gathering stage of the project and is in the process of consolidating stakeholder inputs and observations from special inspections/studies into categories of performance information. The working group will continue to work on translating the broad insights into specific recommendations to be included in the pilot project report.
- Pilot Project 4 working group, led by OAS, on State guidance development has reviewed the prioritized list of regulatory needs developed by the Pilot Project 1 working group and identified I-125 seed localization of non-palpable breast lesions as its candidate for licensing and inspection guidance development. Pilot Project 4 began work to develop licensing and inspection guidance for this medical modality in March 2004.
- Pilot Project 5 working group, led by NMSS, on revised IMC 2800, Materials Inspection Program, has completed its tasks in revising the IMC 2800 and 12 associated routine inspection procedures for medical and non-medical types of use. The revised materials inspection program is currently being implemented by the NRC regional offices, however the working group has not determined the extent of Agreement State implementation of the program.

Future Actions

The working groups for the pilot projects are finalizing their pilot project reports, which include an analysis against the success measures as set forth in SECY-02-0074, and recommendations to be considered by NRC and Agreement States. The working groups for Pilot Projects 2, 3, and 5 expect to complete their reports by April 15, 2004. The extent of Agreement State implementation of the revised materials inspection program developed in Pilot Project 5 will be determined and reported on in the November 2004 Commission Paper.

The working group for Pilot Project 1 expects to finalize its pilot project report in September 2004. To fully explore the viability of the process developed in Pilot Project 1, a means for integration into the planning and budgeting processes of both the NRC and the Agreement States is required. Fully testing this process can be accomplished during the next budget cycle in FY05. Due to earlier delays in starting work, the Pilot Project 4 working group will develop a schedule (work product plan) and expects to finalize its pilot project report during the summer of 2004.

A stakeholders' meeting was held on March 31, 2004. The purpose of the meeting was to inform stakeholders of the status and progress of the pilot projects and to receive feedback on the structure and framework of the NMP. Information on the Stakeholder's Meeting will be considered by each working group and will be reflected in the final report to the Commission.

In addition, staff is reviewing the experience of NRC and State staff working on the Materials Security Working Group and identifying lessons learned that can be applied to the NMP. Staff will also address the February 13, 2003, SRM, "Briefing on Status of the Office of Nuclear Materials Safety and Safeguards Programs - Materials Safety," in its final report to the Commission.

RESOURCES:

Staff estimates that 1.0 FTE for FY 2004 is required to work on the five pilot projects. Minimal resources will be needed in FY 2005 with the scheduled November 2004 date for the final report. Resources currently identified in the budget for NRC/State working group activities are adequate to cover NRC resource needs for the pilots. NRC costs for the pilot projects include travel and per diem for State staff participation, and are included within STP's current invitational travel budget.

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 Boards of Directors.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. NMP Pilot Projects Implementation Plan
2. Pilot Projects Milestones and Schedule
3. Pilot Projects 1-5 Status Reports

NATIONAL MATERIALS PROGRAM PILOT PROJECTS IMPLEMENTATION PLAN

The Nuclear Regulatory Commission (NRC), the Organization of Agreement States (OAS), and the Conference of Radiation Control Program Directors (CRCPD) are working together on five National Materials Program (NMP) pilot projects using a blend of the “Current Program” and “Alliance” Options to test how well NRC and Agreement States can collaborate in the identification of work products and establish priorities for products needed in the materials program, and demonstrate the parties’ ability and willingness to participate and accept products.

Background

The “National Materials Program” is a term developed to define the broad collective framework within which both the NRC and the Agreement States function in carrying out their respective radioactive materials regulatory programs. Such a framework also includes the OAS and the CRCPD. The NMP defines the day-to-day activities carried out by a radioactive materials regulatory program, such as licensing and inspection activities. It also defines responsibilities shared by federal and state programs to help maintain an adequate national base of rules and guidance needed for effective program operation.

In November 1999, NRC Commissioners (Commission) approved the staff plan (SECY-99-250) to form a working group to address the impacts of the increased number of Agreement States and to provide advice to the NRC on the NMP.

The NMP Working group, which included six representatives from States, six NRC representatives, and an NRC advisor, completed its Final Report in May 2001. After evaluating comments from stakeholders, considering the advantages and disadvantages for each of the structural options, and the potential resource implications for each option, the working group provided its final report and recommended that the Commission adopt the Alliance Option (SECY-01-0112). The Alliance Option is a structure in which the Agreement States collaborate and participate with the NRC and assume and carry out a greater responsibility for developing rules and guidance needed for an effective consensus process for the NMP.

Subsequently, the NRC staff, and OAS and CRCPD Boards 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 Addendum to SECY-02-0074 was issued on June 18, 2002 (SECY-02-0107) to request Commission approval of the staff’s and OAS and CRCPD Boards’ recommendation for using a blended approach of the “Current Program” and “Alliance” options to carry out the pilot project. The Commission approved implementation of the blended approach on August 20, 2002.

The five pilot projects are:

1. Develop a process that could be utilized by NRC and the Agreement States in the establishment of priorities for the development of materials policy, rulemakings, and guidance products.
2. Assumption by Agreement States/CRCPD of lead responsibility for the oversight of a national radiographer certification program, which includes the review and approval of state government and independent organizations' initial applications to be recognized as certifying entities, review of subsequent program changes, and the responsibility for follow-up evaluations of program activities such as test administration and program maintenance.
3. Participation of Agreement States and NRC in a joint process to evaluate the collective set of Agreement State and NRC licensee events for possible generic implications and possible additional regulatory action as part of a nationwide operating experience evaluation program.
4. Assumption by an Agreement State of responsibility for development of licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved.
5. Implementation of specific Phase II recommendations, including ongoing work of the existing working group to draft and pilot test revisions to IMC 2800.

In analyzing the success of NRC/State cooperative efforts, the Commission also recommended that interactions between NRC and the States addressing additional security measures for materials licensees be studied and lessons learned applied to the NMP (SECY Suspense 1999900114, August 20, 2002.) This effort is being lead by the NRC Office of State and Tribal Programs (STP) and is not part of the NMP pilot projects.

Initial Process For Development of the Implementation Plan

Two participants in the Senior Executive Service Candidate Development Program have worked in succession over a seven month period with STP staff, and the OAS and CRCPD Boards to help guide the pilot projects through a range of activities, including finalization of the pilot project Charters, development of an implementation plan, and monitoring and management to ensure that timely progress on each of the pilot projects is made.

Pilot project Chairs were confirmed in November 2002. They are:

- Pilot Project 1 Co-Chair – Shawn Smith, Physicist, NRC/STP
Co-Chair – Ruth McBurney, Director, Division of Licensing,
Registration and Standards, Bureau of Radiation Control
Texas Department of Health
- Pilot Project 2 Chair – Jan Endahl, Manager, Industrial Radiographer Certification,
Bureau of Radiation Control, Texas Department of Health

Pilot Project 3 Co-Chair – Michael Markley, Senior Project Engineer
NRC/Office of Nuclear Material Safety and Safeguards (NMSS)
Co-Chair – Marcia Howard, Administrator
Nuclear Materials Safety Program, Ohio

Pilot Project 4 Chair – Robert Gallagher, Radiation Control Officer, Radiation Control
Program, Massachusetts Department of Public Health

Pilot Project 5 Chair – Thomas Young, Health Physicist, NRC/NMSS

NRC/STP staff met with the pilot project Chairs and State staff to begin planning for organizing the pilot project activities into a comprehensive project starting with finalizing the Charters and resulting in analyses of the success of the pilot projects, recommendations and plans for the future of the NMP, and a final report to the Commission. On November 25-26, 2002, NRC/STP staff and Marcia Howard, Administrator, Nuclear Materials Safety Program, Ohio, met to draft an outline and schedule for an implementation plan. Using this draft, NRC/STP staff met in person or held a teleconference with each pilot project Chair to refine the first draft of the implementation plan, and arranged a teleconference on December 12, 2002, to finalize the basic plan and several major milestones. Refinement continued through the use of e-mail.

To help ensure balanced working groups, a letter to the OAS and CRCPD Chairs, and a memorandum to NRC Offices (Directors of NMSS, Office of General Council (OGC), Office of the Chief Financial Officer (OCFO); and Regional Office Administrators) was issued on January 29, 2003, by the Director, NRC/STP, to provide the final basic pilot project Charters, Implementation Plan, and to request working group members, where needs existed.

Development of Work Product Plans for Each Pilot Project

One key milestone is the development and approval by NRC, OAS and CRCPD of a work product plan for each pilot project. The pilot project Chair has responsibility to prepare a work product plan based on the basic pilot project Charter and input/participation by working group members. The work product plans, which are due to be completed and submitted with the Basic Charters to NRC/STP, OAS and CRCPD Chairs for concurrence by March 28, 2003, will guide implementation of each pilot project.

Monthly Meeting Progress Reports

To help manage individual pilot projects and this overall NMP project, the pilot project Chairs will participate in progress meetings, normally by conference call. Since March 19, 2003, pilot project Chairs and NRC/STP staff have participated in a monthly progress meeting by conference call. NRC/STP staff will make the arrangements and additional teleconference calls will be held on the third Wednesday morning of the month, continuing as necessary. The meetings are to be held monthly, with the long term schedule to be developed to meeting the needs of the Chairs, and as necessary for sharing of information.

Travel

NRC/STP will fund travel and per diem to pilot projects working group meetings for State employees who are members of the working groups. Pilot project Chairs will first notify the Director, NRC/STP, of meeting dates and State participants, and after acknowledgment, contact the NRC/STP Management Analyst (bgu@nrc.gov, 301-415-2348) to make specific travel arrangements.

Time and Labor Data For Working Group Participation

For use in reporting and analyses of the pilot projects, time and labor data will be collected for each working group participant. Each Chair will periodically (monthly suggested) collect information, in terms of hours worked, from each State participant. For NRC working group participants, the following time and labor codes have been established:

| | |
|--------|--|
| J00177 | National Materials Program - Working Group (for work on the overall project, e.g., implementation plans, work on Commission paper, monthly progress reporting teleconferences) |
| J00183 | Establishment of Priorities (Pilot No. 1) |
| J00184 | National Radiographer Certification (Pilot No. 2) |
| J00185 | Operating Experience Evaluation (Pilot No. 3) |
| J00186 | State Guidance Development (Pilot No. 4) |
| J00187 | Revised Materials Inspection Program (Pilot No. 5) |

Each Chair will inform their NRC working group members of the need to record their time spent on the pilot projects and of the appropriate time and labor codes to be used. Time spent on work which supports the pilot project but which would be accomplished by the individual as a part of his/her normal work should not be recorded using the above codes, but rather should be recorded using the normally used codes. State staff time will be recorded separately.

Communications Plan/Stakeholder Involvement

The CRCPD and OAS Boards, and NRC, OAS and CRCPD, and individual State staffs have worked together to develop the following steps to ensure an appropriate level of communications and involvement of stakeholders:

1. OAS Meeting

The Director, NRC/STP, made a presentation on the NMP and the pending pilot projects at the annual OAS meeting, on October 1, 2002. OAS members were surveyed for their interest in participating in the pilot projects.

2. Advisory Committee on Medical Use of Isotopes (ACMUI) Meeting

The Director, NRC/STP, made a presentation on the NMP and the pending pilot projects at the ACMUI meeting, on October 28, 2002. ACMUI provided comments/input after the meeting.

3. NRC Web Site

The NRC's NMP web site will be revitalized and used to post materials and documents for use by the pilot project Chairs, meeting notices, and to solicit comments on the resultant reports from a broad range of stakeholders.

4. Working Group Meetings

Working group meetings will be open to the public in accordance with NRC Management Directive 5.3, "NRC/Agreement State Working groups." In some cases, meetings may be closed in part or whole, when the working group is discussing predecisional information.

5. Federal Register Notice

The NRC will use the Federal Register to post, for interested parties, a notice that will inform interested parties about the pilot projects and opportunities to provide input, and that notices for pilot project working group meetings will be posted on the NRC's NMP web site.

6. Special Interest Session at Annual CRCPD Meeting

The pilot project Chairs and NRC/STP will participate in a special interest session at the annual CRCPD meeting in May 2003 to discuss the pilot projects. Participation in the May 2004 meeting is also anticipated. The Chairs will present status reports on their pilot project work, take questions and comments, and use the opportunity to get stakeholder feedback.

7. Briefings at OAS

Another opportunity for providing information to stakeholders is the annual meeting of the OAS, which occurs each October. The format is to be determined, but may be a presentation to update status and bring any appropriate issues to the stakeholders, during a general session. In combination with the CRCPD briefings in May, these presentations will ensure that stakeholders receive a face-to-face briefing every six months while the pilot projects are being carried out.

8. RAD_RAP

Another means of obtaining stakeholder involvement in the pilot projects is through the use of the RAD_RAP, an electronic forum for sharing information among State regulators administered by OAS. This system, which has a membership limited to State

and Federal regulators, will be used to post messages about items appearing on the NRC NMP web site, or by individual Chairs to post pilot project products for input.

9. Informational Updates During Monthly OAS/NRC Teleconferences

NRC/STP staff, and pilot project Chairs, as available, will participate in the monthly OAS/NRC teleconferences, to provide a brief update of progress for the benefit of State officials and NRC managers.

10. Other Opportunities For Stakeholder Input

NRC staff and the pilot project Chairs will also seek other opportunities for input by stakeholders, including licensee representatives, ACMUI and ACNW.

Milestones and Schedule

The following key milestones and schedule were developed by NRC and State staff, including the pilot project Chairs (See Attachment 2 for a detailed description of each milestone and schedule, and each Charter):

| | |
|---------------------|--|
| January 15, 2003 | Finalize Basic Charters |
| January 23, 2003 | Finalize Implementation Plan |
| February 28, 2003 | Submit Commission Notation Vote Paper to Commission |
| March 19, 2003 | Hold first monthly progress meeting by conference call |
| May 4-7, 2003 | Brief at CRCPD meeting |
| October 14-17, 2003 | Brief at OAS meeting |
| February 2, 2004 | Complete draft pilot project reports |
| March 31, 2004 | Submit Progress Report to the Commission |
| April 15, 2004 | Complete final pilot project reports/products for submission for approval of NRC/STP, NRC Offices, OAS and CRCPD |
| May, 2004 | Brief at CRCPD meeting |
| August 31, 2004 | Integrate comments and complete the Commission report to begin review and concurrence process |
| November 12, 2004 | Submit final report to Commission |

Future Updates to the Implementation Plan

This Implementation Plan will be updated and distributed to pilot project Chairs, as necessary to address additional administrative issues and changed conditions. Any changes will be discussed with the pilot project Chairs in person, by teleconference, or by e-mail prior to incorporating such changes.

PILOT PROJECTS IMPLEMENTATION PLAN: MILESTONES AND STATUS

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, by February 28, 2003 **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)¹
Status: Completed 4/25/03

ATTACHMENT 2

¹The Notation Vote Paper was replaced by a Memorandum to the Commission.

8. Submit nominations for membership on pilot project working groups to NRC/STP February 28, 2003 (NRC Offices, OAS and CRCPD Chairs)

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.

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: To Be Determined
 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 WPP) on 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) on 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) on 7/9/03; STP: 7/14/03;
NMSS: 7/25/03; OAS: 7/14/03; CRCPD: 7/21/03

Pilot Project 4: TBD

Pilot Project 5: requested concurrence (Charter 6/20/03, WPP 7/9/03) 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: Completed
Pilot Project 1: 2/2/2004
Pilot Project 2: 2/2/2004
Pilot Project 3:
Pilot Project 4: To Be Determined
Pilot Project 5:

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 *no later than* **March 15, 2004** (NRC: STP, NMSS and OGC; OAS and CRCPD)
Status: The draft pilot project reports on pilot project 1 and 2 are currently under review by STP.
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.
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)
28. Brief at CRCPD meeting **May, 2004** (NRC/STP and Pilot Project Chairs)
29. Complete draft report to the Commission and distribute for review by Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS, and CRCPD **June 15, 2004** (NRC/STP)
30. End of comment period for draft report to the Commission **July 30, 2004** (Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS and CRCPD)
31. Integrate comments submitted by Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS and CRCPD, and complete the report to the Commission **August 31, 2004** (NRC/STP)

32. Obtain comments and concurrences of Pilot Project Chairs, NRC/OGC, NRC/NMSS, OAS and CRCPD on final report to the Commission, to NRC/STP Director
September 30, 2004 (NRC/STP)
33. Obtain concurrence of NRC/STP Director and submit final report to NRC/EDO
October 20, 2004 (NRC/STP)
34. Submit final report to the Commission **November 12 , 2004 (*critical date*)** (NRC/EDO)

PILOT PROJECTS 1-5 STATUS REPORTS

Pilot Project 1: Establishment of Priorities

Objectives

- 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.
- 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.
- 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).

Scope of Work

- Obtain information and develop understanding of the processes utilized by NRC and the Agreement States to establish work priorities for the materials program.
- 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.
- 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).

Current Status

- **Progress**

The Pilot Project 1 working group, established in March 2003, first examined current processes used by NRC and Agreement States to establish their agencies' priorities and developed a course of action for the pilot. In June 2003, the working group collected lists of regulatory needs from most NRC offices and Agreement States, and one non-Agreement State, and compiled a collective list. From the list, a prioritization package was developed. The package consisted of identified regulatory needs, a worksheet for evaluation, and a list of regulatory needs currently being addressed by joint working groups.

In September 2003, the prioritization package was sent to all Agreement State radiation control program directors and to the directors of NRC materials offices and regions, with directions for completion. For every regulatory need listed in the worksheet, the respondents were requested to assign a level of priority as the need related to three performance goals: protection of public health and safety, security of radioactive materials, and efficiency and effectiveness. The Working group found that these three goals collectively represent the range of goals used by NRC and Agreement States. By November 2003, all of the NRC offices responded, as well as most of the Agreement State programs. The working group analyzed the results of the prioritization packages to create a prioritized list of regulatory needs.

In parallel with the development of the prioritized list, the working group also developed a proposed framework and process that NRC and the Agreement States could use to prioritize regulatory needs in a National Materials Program (NMP) under the Alliance Option. The process was presented during a briefing of NRC Management and the boards of the OAS and CRCPD in September 2003, and at a workshop in October 2003 to State and Federal personnel attending the annual OAS meeting. Comments received during the briefing and workshop were incorporated into the proposed framework and process.

- **Successes and Challenges**

The working group faced several challenges in the implementation of the pilot project. One challenge was to obtain full participation in the development of a process to establish priorities for the NMP. A key to the success of the NMP is the support and participation from its stakeholders. The working group sometimes had difficulty obtaining full participation from the stakeholders involved. For example, in June 2003, the working group requested that each NRC Office involved in the NMP and all States submit a list of regulatory needs. The working group received responses from about 50 percent of those solicited. Lack of participation was due, in part, to time constraints and the perceived lack of relevance to individual Agreement State programs. Through meetings with NRC management, OAS, and CRCPD, the working group eventually achieved support from stakeholders and a higher degree of participation (80 percent).

Another challenge was the ability to define the regulatory needs that should be included

in a NMP. In defining the regulatory needs, the working group was to develop a list relevant to both NRC and Agreement State radioactive materials programs. The working group decided to only include material for which both NRC and Agreement States have regulatory authority, excluding material such as naturally occurring and accelerator-produced radioactive material. In addition, the working group found that a large majority of the regulatory needs identified were currently being addressed. The working group then decided to exclude those needs which were being addressed in other NRC and Agreement State working groups. Although challenges were incurred throughout the implementation of the pilot project, the working group was able to demonstrate that a process could be developed to meet the objectives and scope of work.

! Resources

The working group reduced travel costs by utilizing conference calls to conduct work related to the project. Four interface meetings were held: three in Rockville, Maryland; one in Austin, Texas. The estimated resources for the working group include 384 hours per each member, and 480 hours per co-chair. As of March 6, 200, there were a total of 1,615.5 hours worked on pilot project 1.

Path Forward

The Working group will complete the refining and testing of all steps of the proposed prioritization process, as requested by NRC management, and the Chairs of OAS and CRCPD in February 2004, and finalize the pilot project report. The report will provide recommendations for the priority-setting process in a NMP under the Alliance Option. Due to additional work to refine and further test the proposed process, as requested by NRC management, OAS, and CRCPD, the report is expected to be completed by September 2004.

Expected Final Work Products

The work products of the Pilot Project 1 working group will include: (1) a prioritization 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 reflecting both NRC and Agreement States regulatory needs, and (3) a proposed framework, which could be used by NRC and the Agreement States to reach decisions on which work items identified in the joint prioritization of regulatory needs would be initiated, and who would be responsible for completing the work, for the NMP under the Alliance Option.

Pilot Project 2: National Industrial Radiographer Certification Program

Objectives

The purpose of this pilot project is to have the CRCPD, through the G-34 Committee on Industrial Radiography, serve as the lead organization for the oversight of all activities associated with a national industrial radiographer safety certification program. The oversight activities include the:

- (1) review and approval of State government and independent certifying entities' initial requests to be recognized as certifying entities;
- (2) review and approval of subsequent program changes; and
- (3) authority to conduct follow up evaluations of program status, including test administration and program maintenance activities.

Scope of Work

The initial working group action was to formalize the criteria, based on nationally-accepted standards, and develop a process for conducting the initial application reviews. The working group used 10 Code of Federal Regulations, Part 34, Appendix A as the basis for the criteria for radioactive materials certification programs, and the equivalent CRCPD document (SSRCR Part E) for x-ray only and combination certification programs.

The working group will make recommendations for evaluating certification programs at predetermined intervals once they are recognized, however, because of project time constraints, follow-up program evaluation activities are not being developed and implemented as part of this project.

The second phase of the project was to apply the criteria and process when reviewing a test case and evaluate its effectiveness. The working group identified three options for testing its criteria: review a new application or proposed program change; evaluate the process previously used in reviewing the American Society for Nondestructive Testing, Inc.'s (ASNT) request to be recognized as a certifying entity; or apply the criteria and review process to an existing State certifying entity.

Current Status

The working group completed both phases of its project and submitted a draft of its final pilot project report and work products to STP, on February 2, 2004, for review.

- **Progress**

The working group used the criteria previously established by an NRC working group in 1997 during its review of ASNT's request to have its radioactive material certification program nationally recognized. For certification programs involving radioactive materials and/or x-ray machines, the working group revised the criteria previously established by CRCPD's G-34 Committee on Industrial Radiography when it reviewed ASNT's request in 2000 to have its x-ray and combination certification programs recognized.

The G-34 Committee had also previously developed process flow charts for States and for independent organizations seeking recognition of their certification programs. The working group further refined these flow charts.

Although the working group did not implement the mechanics of the sequence of events for initial approval or subsequent program changes, it was able to enlist the participation of a State having an existing certification program to test its revised criteria. As added interest and information, the working group solicited feedback from the remaining State certifying entities, the ASNT, and the Canadian Nuclear Safety Commission.

- **Successes and Challenges**

Successes:

- (1) Seven of ten States polled indicated they would participate as the test case for applying the criteria to their certification programs.
- (2) Teleconferences were coordinated by NRC, were well attended by working group members, and were an extremely cost efficient and time saving alternative to traveling to meetings.
- (3) Working group members, recognized as a "center of expertise," have a stake in the outcome of this project, regardless of their organization affiliation, and were active participants in the process.
- (4) The CRCPD Board of Directors responded quickly to requests for review and approval of the working group's Charter and Work Plan, and transmitted its written decisions back to the Chair.
- (5) The NRC project coordinator organized and transmitted project information to NRC, CRCPD and OAS personnel, as well as coordinated meetings and updated the web site -- all of which helped to lessen the administrative reporting duties of the project chair.
- (6) Issues associated with the reciprocal recognition of Canadian certifications were shelved due to the lack of response from the Canadian government on the working group's invitation to participate in the pilot project.

- (7) The working group has identified additional work that should be accomplished in the future in order to remain responsive to the issues surrounding certification, and to realize the benefits that a national program would offer.

Challenges:

- (1) The change in project leadership (four new individuals within nine months) was disruptive to the forward progress of the project, and required additional time and effort to brief the new leaders.
- (2) The expectations of the NRC were not always clear, e.g., the success measures as stated in SECY-02-0074. The success measures, as written, were ambiguous, often contradictory within the same question, and called for speculation on the part of the working group in answering what the group thought NRC's action would be. Clearly, no one on the working group is in a position of authority to dictate NRC policy decisions or agency direction. The working group had several discussions on the interpretation of the success measures, and had requested guidance from NRC during a discussion between the project chair and the coordinator to attempt to clarify the wording and intent of the success measures. Ultimately, the project chairs were told during one of the monthly progress telephone conferences to just go with the existing success measures, as stated.
- (3) Being one of initially five projects, artificialities in process and reporting were created for the group as a whole, rather than accommodating the progress and nature of the individual projects. The working group did not receive any written communication from NRC in response to requests for review and approval of the charter and work product plan, as was provided by CRCPD. Additionally, the completion dates for the concurrences from NRC that appeared in the Implementation Plan Milestones and Schedule lagged well behind those of the CRCPD.

- **Resources**

The original estimate of time per person for this project was 208 hours, excluding travel time. As of March 6, 2004, there has been a total of 1,160.6 hours worked on pilot project 2. The working group met twice in person (Rockville, Maryland, and St. Rose, Louisiana).

Path Forward

The working group will finalize the pilot project report, including an analysis against the success measures as set forth in SECY-02-0074, and provide its conclusions and recommendations for future activity by the group. The working group will submit the final report by the April 15, 2004, target date.

Expected Final Work Products

The work products of Pilot Project 2 will be:

Work Product One: revised program review criteria and certification process flowcharts;

Work Product Two: the working group's evaluation of applying the review criteria to an existing State's certification program, along with the degree of participation from the contacted States, types of feedback received from the States and ASNT, and the working group's conclusions and recommendations for future actions

Pilot Project 3: Operating Experience Evaluation

Objectives

The objective of the Operating Experience Evaluation Pilot was to optimize the common use of operating experience information from licensed facilities and trending in integrated NRC and Agreement State review, assessment, and decision-making processes. The pilot was designed to examine current programs and to develop strategies and tools to make the programs more scrutable, predictable, and transparent. The revised process should produce consistent analyses and results when implemented by the NRC or Agreement States.

The outcome of the pilot should be a set of program recommendations, for consideration by the NRC and Agreement States, to enhance regulatory procedures, organizational review and evaluation methods, sources of information, and methods to better communicate operating experience information. Recommendations should contribute to advancement of safety, security, openness, regulatory and management effectiveness and efficiency.

Scope of Work

For the purpose of this pilot, the working group considered operating experience information to include: domestic and foreign event data, major team inspections and special studies leading to generic reviews and/or generic communications, industry-wide analyses of performance and trends, insights and metrics amenable to risk-informed decision making, and performance indicators and associated thresholds for increased regulatory attention.

The Work Product Plan was designed to evaluate regulatory processes and methods to address the following questions:

- (1) How can operating experience information be better communicated between NRC and Agreement States?
- (2) How can operating experience information and trending optimize NRC and Agreement State resource utilization?
- (3) How can risk insights be better integrated into regulatory decision making?

The pilot pursued a sampling approach to addressing these questions. The working group conducted interviews and surveys with regulatory personnel to assess end-user decisions (i.e., inspectors, reviewers, managers), evaluated findings and insights from incident or working group reports (augmented inspection teams, incident investigation teams, etc.), and examined selected areas of regulatory oversight (e.g., portable gauges and intravascular brachytherapy) to examine the use of operating experience information in integrated decision-making processes.

Current Status

The pilot project sought broad stakeholder input in conducting the pilot. The working group made presentations at meetings of the CRCPD, OAS, and Advisory Committee on the Medical Use of Isotopes (ACMUI). The working group held a public teleconference to discuss analysis of operating experience information performed by the University of Texas for the States of Texas and Maine. The working group also participated in deliberations of the NMSS Operating Experience Committee that considered the impacts of the independent evaluation of the Reactor Operating Experience Task Force Report, resulting from the Davis-Besse reactor vessel head degradation incident.

- **Progress**

The information gathering stage of the pilot project is complete. The working group is in the process of consolidating stakeholder inputs and observations from special inspections/studies into categories of performance-related information. While broad insights were gained, more work is needed to translate the insights into value-added recommendations for consideration by NRC and Agreement States in a final pilot report.

- **Successes and Challenges**

- (1) *Communication:* Early in the pilot, it was recognized that the major challenge was communications. Outside the NRC and in some non-reactor parts of the NRC, there is not a common understanding of “operating experience information” and its use. Both NRC and Agreement States do many things well but do not necessarily communicate issues and concerns in a timely manner.
- (2) *Participation:* Substantial challenges exist for NRC and Agreement States to participate in working groups and pilot projects. Currently, these activities are conducted with existing resources, in most cases, as an added activity for most participants. The pilot expects to make recommendations for an operating experience program that can achieve incremental gains over time, whereby a more open partnering process would exist and needs to be supported explicitly in the budgeting process.
- (3) *Operating Experience Clearinghouse:* Individually, NRC and Agreement States perform the necessary functions and process elements of operating experience evaluation. However, challenges exist in sharing information and results in the context of an integrated NMP. The pilot working group sees merit in having a central clearinghouse to serve as a focal point for communicating and coordinating a wide range of information needs across NMSS, STP, and the States.
- (4) *Data Evaluation and Trending:* The Nuclear Materials Event Database (NMED) serves as the only database broadly available for use by NRC and Agreement States. To the extent that NMED meets its original design mission, it is successful. However, NMED can and should evolve to better facilitate trending, operational histories, precursor events, and the development of performance indicators.

- (5) *Generic Communications:* The use of NRC Bulletins and Generic Letters (GLs) is rare in nuclear materials, unlike their use for reactor licensees. Neither NRC nor Agreement States have sufficient resources to follow-up on a large population of issues if the threshold for Bulletins or GLs were lower. Most materials-related generic communications are information notices (INs) and regulatory issue summaries (RISs) that do not require follow-up. One notable observation is that materials INs and RISs lack a degree of specificity with regard to prior operating experience events.
- (6) *Use of Risk Information:* 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.
- (7) *Consistency:* For many years, NRC has strived to achieve regulatory consistency across four, and previously five Regions. In extending regulatory authority to 33 Agreement States, a certain tolerance for variability needs to exist above certain thresholds. Confidence must exist in the results of periodic assessments and in actions taken to address observed deficiencies.

- **Resources**

The working group included equal representation by NRC and Agreement State representatives. The Co-Chairs of the working group represented both NRC and Agreement States, and the working group was composed of one Agreement State and NRC Regional representative.

This pilot project was conducted entirely through the use of electronic media. No team meetings involving travel were held. This pilot demonstrated the ability of working groups to be conducted cost effectively through biweekly conference calls without undue burden on NRC or Agreement State participants. As of March 6, 2004, a total of 422.1 hours were expended on pilot project 3.

Path Forward

The working group plans to reconcile stakeholder inputs and observations from special inspections and studies into categories of performance-related information. Preliminary recommendations will be developed and compared against performance measures in SECY-02-0074, "National Materials Program: Pilot Projects."

Expected Final Work Products

The final work product will be a set of recommendations for consideration by the NRC and Agreement States, to enhance regulatory procedures, organizational review and evaluation methods, sources of information, and methods to better communicate operating experience information. The final work product will be developed in accordance with the NMP Implementation Plan.

Pilot Project 4: State Guidance Development

Objective

To identify an implementation strategy for Pilot Project 4, as defined in SECY-02-0074, and to develop licensing and inspection guidance for a new use of material, or new modality, not previously reviewed and approved by the NRC and Agreement States.

Scope of Work and Work Products

Under this pilot project a group of Agreement State staff will develop licensing and inspection guidance for a new use of material, or new modality, not previously reviewed and approved by the NRC.

Planned accomplishments include:

- (1) Survey the Agreement States, NRC Headquarters, and the NRC Regions to ascertain if there is a new use of material or new modality that would qualify under this pilot project;
- (2) The OAS Executive Board will assign a chair for the working group;
- (3) The Chair will identify which medical modality to be used for the Pilot Project from the list of potential modalities as a result of the survey completed in Objective 1. Once the medical modality has been identified, Agreement States (and the NRC Regions) will be solicited for volunteers to the working group;
- (4) The working group will develop inspection and licensing guidance for the new modality and work with the OAS and NRC to determine the process for accepting the guidance and incorporating it into the existing licensing and inspection system.

Current Status

- **Progress**

The OAS Executive Board approved Robert Gallagher as the new Chair of the working group, replacing Kathy Allen.

Pilot Project 1 performed a survey of Agreement States, NRC Headquarters and Regional offices to identify their regulatory needs. The results of this survey indicated a high level of interest in the development of licensing and inspection guidance for new medical technologies, including medical devices and procedures. Examples provided by respondents included Y-90 therapy microspheres, Gliasite procedures involving balloons filled with I-125, new radioisotopes using monoclonal antibodies techniques, non-coronary application for IVB, and Sr/Rb generators. In March 2004, the working group identified I-125 seed localization of non-palpable breast lesions as its candidate for licensing and inspection guidance development.

Members of the working group were solicited from Agreement States and the NRC. The working group was established on January 30, 2004, with members representing the States of Florida, Georgia, and Illinois, and NRC Region III.

- **Successes and Challenges**

The most significant challenge faced by the Pilot 4 working group is the existing milestone timetable. A draft pilot project report and work products, including an analysis against the success measures as set forth in SECY-02-0074, was due February 2, 2004. Due to earlier delays in starting work, the Pilot 4 working group was not able to hold its first teleconference call until after this date, and did not have its first meeting until March, 2004. The working group therefore seeks an extension on most of the 2004 milestones schedule. The working group will pursue a schedule that shifts most 2004 dates contained in the NMP Implementation Plan, while holding to the November 12, 2004 milestone of submitting the final report to the Commission.

- **Resources**

Each working group member anticipates spending up to 40 hours on the initial drafting/reviewing process during the spring of 2004, and possibly up to 20 hours in late spring/early summer 2004 to finalize the Draft. All times are reasonable approximations. As of March 6, 2004, there has been a total of 166 hours worked on pilot project 4.

Path Forward

The working group held its first conference call in February, 2004 (due to conflicts with members' schedules). The purpose of the teleconference call was to discuss the various modalities and choose one for the Pilot to focus on, to draft a work product plan, and to make arrangements to hold a first meeting.

The working group held its first meeting in Florida during the week of March 15, 2004. The group used this meeting to complete a draft work product for the selected medical modality.

The work product will be provided to the OAS and NRC for review and comment. Comments received from the OAS and NRC will be reviewed by the working group and incorporated into the guidance document.

Expected Final Work Products

The working group will develop licensing and inspection guidance for I-125 seed localization for non-palpable breast lesions and work with the OAS and NRC to determine the process for accepting the guidance and incorporating it into the existing licensing and inspection system.

Pilot Project 5: Revised IMC 2800, Materials Inspection Program, and the associated routine inspection procedures

Objectives

- (1) To revise IMC 2800 and its associated non-medical Inspection Procedures (IP) and non-medical Temporary Instructions (TI) in order to align the materials inspection program with a more risk-informed and performance-based regulatory approach.
- (2) To implement Phase I and Phase II recommendations and conserve resources for the materials program in FY02 and thereafter.
- (3) To incorporate innovative approaches not included in Phase I and II recommendations for the implementation of the inspection process to achieve long-term increases in effectiveness and efficiency.
- (4) To solicit Agreement State participation for the work described below in order to obtain information on the feasibility and viability of the NMP-“Alliance” Option.

Scope of Work

- (1) The Writing Team (WT) revised IMC 2800, IP 87110-series, and the non-medical IPs to incorporate the Phase II recommendations that specifically addressed IMC 2800 to:
 - revise inspection priorities
 - empower inspectors
 - streamline inspection preparation
 - provide flexibility for scheduling initial inspections
 - provide flexibility for scheduling field office inspections
 - expand the use of NRC Form 591, Safety Inspection Report and Compliance Inspection
- (2) The WT used the risk-informed inspection priorities determined by the Phase II Review Group without specifically validating the priorities for the revised materials inspection program. The validation issue will be revisited by another team at another time in the future.
- (3) The WT adopted the core performance elements recommended by Phase II. During each inspection, the inspector will evaluate licensee performance for each element. Each revised IP provides guidance for the inspectors for the following core performance elements:
 - security and control of licensed material
 - shielding of licensed material
 - comprehensive safety measures
 - radiation dosimetry program

- radiation instrumentation and surveys
 - radiation safety training and practices
 - management oversight
- (4) The WT initiated a Temporary Instruction for the revised Materials Inspection Program (TI 2800/033) in order to evaluate resource savings for the materials program. The selected Phase I and II recommendations for IMC 2800 were incorporated into TI 2800/033. The revised IPs were implemented under the TI.

The revisions to the IP 87110-series did not include interim compensatory measures (ICM). A separate TI may be developed by other staff for the ICM. However, if information is available from staff actions regarding security that could influence the routine inspection program, this information will be considered in a future version of IMC 2800.

The WT revised the seven non-medical IPs (87110, 87111, 87112, 87113, 87114, 87117, 87120) and coordinated with another writing team that revised the four medical IPs (87115, 87116, 87118, and 87119) to align with revised Part 35.

- (5) The WT analyzed TI 2800/033 and the revised IPs and prepared final versions of IMC 2800 and the associated routine IPs and addressed the success measures for the NMP Pilot Projects.

Current Status

- **Progress**

The materials inspection program has been revised and is being implemented by the NRC regional offices. Revised inspection documents are available in the NRC Inspection Manual on the NRC external web page, i.e., IMC 2800 and 12 associated routine inspection procedures for medical and non-medical types of use. The final report for TI 2800/033 has been prepared and addresses the success measures for the NMP Pilot Projects.

- **Successes and Challenges**

Successes

- (1) Evaluation of the TI indicated gains in efficiency and effectiveness. The overall labor rate was reduced ~ 15 percent and was influenced mostly by streamlining the administrative procedures for preparation and documentation of inspections which indicated a reduction of ~ 30 percent. The onsite inspection time was reduced ~ 10 percent by implementing a more performance-based approach. All the regional offices indicated a reduced labor rate.
- (2) The routine inspection intervals were adjusted to achieve a more risk-informed approach and regional management discretion was preserved to reduce the

inspection interval when a licensee's inspection history indicates poor performance of radiation safety.

- (3) The WT developed uniform training modules to explain revised IMC 2800 and the revised routine IPs to regional inspectors and supervisors. WT members from the regions provided initial and refresher training for inspectors and served as the point of contact for regional inspectors and supervisors during the pilot period. The training sessions were well attended by the regional inspectors and strongly supported by regional management. This arrangement effectively and efficiently resolved informal comments from inspectors during the pilot period and reinforced implementation of the changes to the materials inspection program.
- (4) The State representative contributed valuable insights for the revised materials inspection program, and thus demonstrated the value of the joint effort. For example, the State representative presented information to the States about the revised materials inspection program and participated as the WT panel member at a CRCPD annual meeting. The State representative presented details of the pilot project, participated in the question-answer session, and solicited the States to provide inspection data to the WT for comparison with NRC data during the final analysis of the TI. The representative developed posters and attended several poster sessions. The State representative also attended training sessions for NRC inspectors in order to present the TI to the States.

Challenges

- (1) Evaluation of the TI indicated that the regional offices did not shed as many inspections as expected. Since 1995, regional inspectors had already extended the next inspection date for a majority of the inspections which reduced the impact of the revised inspection priority code. Also, inspectors continued to work at the same pace and were authorized in many cases to complete inspections ahead of the due dates. Consequently, the number of inspections completed during the pilot period (1456 inspections) was about the same as the number of inspections completed during the pre-pilot period (1470 inspections).
- (2) There was not equal representation from the Agreement States and the NRC for Pilot Project No. 5 because the TI was an existing activity well before the NMP–Pilot Project implementation plan was developed in January 2003. The WT and Pink/Red Team (PRT) were heavily represented by NRC and had previously implemented the action plan to implement the Phase I/II recommendations to revise the materials inspection program. The WT membership included an individual who was appointed by the OAS/CRCPD. However in January 2003, the WT charter was amended to incorporate the NMP–Pilot Projects Implementation Plan. Later in 2003, OAS/CRCPD appointed a manager to participate as a member of the PRT and approved the work products which were developed by the WT and implemented by the regional offices under the TI.

- (3) The revision of the materials inspection program was chartered and generally viewed as an NRC internal function. In June 2002, the NRC invited the States to implement the TI. In June 2003, the NRC invited the States to comment on the work products (revised IMC 2800 and routine IPs) and to provide their inspection data. The WT desired to compare the TI data with the States' inspection data. However, no state responded to these invitations to voluntarily participate during the pilot period and the analysis of the TI. Consequently, no insights are evident from this pilot project for the potential success of the Alliance Option.
- (4) During the pilot period, technical staff from the Office of State and Tribal Programs (STP) completed initial and refresher training for Management Directive 5.6, Integrated Materials Performance Evaluation Program (IMPEP), (MD 5.6) and completed the routine revision of MD 5.6. IMC 2800 is referenced in MD 5.6 for determining the status of a State's materials inspection program. The STP technical staff are to be commended for their efforts to coordinate revised MD 5.6 with the TI and to communicate revised IMC 2800 to the IMPEP trainees.

Resources

About 120 hours were specifically involved the NMP–Pilot Project, as follows:

WT Team Leader ~ 90 hours as of January 2004
WT State Representative at CRCPD Annual Meeting ~ 8 hours
WT members ~ 20 hours, total
Pink/Red Team Reviews ~ 2 hours, total

Path Forward

- (1) The WT Team Leader will continue to be involved with the NMP–Pilot Project Chair activities as indicated in the NMP–Pilot Project Implementation Plan. The regional inspectors are implementing the final versions of revised IMC 2800 and the routine inspection procedures which are available in the NRC Inspection Manual on the NRC web site. The States may adopt the final versions for their materials inspection programs.
- (2) In the future, the NRC should coordinate with the OAS and the CRCPD to ensure voluntary participation by the States. Planning meetings for these entities should include routine discussions about alignment of their respective materials inspection programs to achieve consistency for a risk-informed and performance-based approach to evaluate licensee performance in Agreement and non-Agreement States.

Final Work Products

- (1) IMC 2800, Materials Inspection Program (11/25/03)
- (2) The routine inspection procedures indicated below were replaced by the revised inspection procedures in the NRC Inspection Manual:

| De-Listed Inspection Procedures | New (Revised) Inspection Procedures |
|--|--|
| IP 87120, Industrial Radiography Programs | IP 87121, Industrial Radiography Programs (12/31/02) |
| IP 87112, Irradiator Programs | IP 87122, Irradiator Programs (12/31/02) |
| IP 87113, Well Logging Programs | IP 87123, Well Logging Programs (11/25/03) |
| IP 87114, Fixed and Portable Gauge Programs | IP 87124, Fixed and Portable Gauge Programs (11/25/03) |
| IP 87111, Materials Processor/ Manufacturer Programs | IP 87125, Materials Processor/ Manufacturer Programs (12/31/02) |
| IP 87110, Industrial/Academic/Research Programs | IP 87126, Industrial/Academic/Research Programs (12/31/02) |
| IP 87117, Radiopharmacy Programs | IP 87127, Radiopharmacy Programs (12/31/02) |
| Portions of TI 2800/029, Revision 2 (IP 87115), Nuclear Medicine Programs, which address low-risk, diagnostic nuclear medicine | IP 87130, Nuclear Medicine Programs–Written Directive Not Required (10/24/02) |
| Portions of TI 2800/029, Revision 2 (IP 87115), Nuclear Medicine Programs, which address uses of sodium iodide-131 and therapeutic uses for nuclear medicine | IP 87131, Nuclear Medicine Programs–Written Directive Required (10/24/02) |
| IP 87118, Brachytherapy Programs | IP 87132, Brachytherapy Programs (10/24/02) |
| IP 87116, Medical Teletherapy Programs | IP 87133, Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs (10/24/02) |
| IP 87119, Medical Broad-Scope Programs | IP 87134, Medical Broad-Scope Programs (10/24/02) |

- (3) Final Report for Temporary Instruction 2800/033, Revised Materials Inspection Program