

POLICY ISSUE INFORMATION

May 3, 2002

SECY-02-0074

FOR: The Commissioners

FROM: William D. Travers
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SUBJECT: NATIONAL MATERIALS PROGRAM: PILOT PROJECTS

PURPOSE:

To inform the Commission of five pilot projects the staff is undertaking, in coordination with the Agreement States, to provide additional information to help understand the feasibility and viability of the Alliance Option recommended by the National Materials Program Working Group.

BACKGROUND:

The National Materials Program (NMP) is a term developed to define the broad collective framework within which both NRC and the Agreement States function in carrying out their respective materials radiation control programs. Such a framework also includes the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD). The NMP defines the day-to-day activities carried out by a materials regulatory program, such as licensing and inspection, and more importantly defines additional responsibilities shared by each program to help maintain an adequate national base of rules and guidance needed for effective program operation. The Alliance Option is one of six Options examined by the NMP Working Group (SECY-01-0112). The Alliance Option reflects a continuation of current NRC and Agreement State programs, but work to develop national regulatory products (rules and guidance) and priorities for those products is performed in a collaborative manner. Decisions are based on a participatory process between NRC and the Agreement States, and the Agreement States assume greater responsibility for devoting resources to development of regulatory products.

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DISCUSSION:

The Alliance Option identified in the NMP Working Group Report could represent a possible outcome of continued evolution of the current program. Under the Alliance Option, the level of resources and ability of each regulatory program to commit resources to specific activities undertaken to support a NMP must be known. Some program activities will be common to all programs (e.g., licensing and inspection) and will be budgeted individually by each program based on factors such as the number of licensees and projected workload. Other activities, such as those to address unique technical issues, or to support maintenance of specific rules or guidance, may be unique to a particular program (either NRC or Agreement State), and will need to be specifically budgeted and addressed by that program. However, activities such as the maintenance and update of existing rules and guidance to keep pace with technology and radiation safety research and knowledge can be shared by NRC and the Agreement States within a NMP structure.

Participation by NRC and individual Agreement States in such shared activities will depend on a number of factors, such as the size of the program, available resources, expertise, and willingness of the program to help support the NMP. The level of effort and direct support to the NMP may also vary within each program each year. Some programs may choose to assume the lead in certain areas to help provide solutions to common regulatory or technical issues faced by one or more programs. In other cases, programs may choose to participate on working groups to develop model solutions to common problems. Finally, regardless of the collective effort to develop products which can be used by all programs, each program will need to take action to incorporate such products into their individual program format (e.g., issue as a program guidance document or promulgate as a program rule) and then take the necessary steps to implement the products through normal processes, such as publication and providing copies to stakeholders and licensees.

Under Section 274 of the Atomic Energy Act of 1954, as amended (Act), NRC also has programmatic responsibility to periodically review the actions of the Agreement States to comply with the requirements of the Act to continue to maintain adequate and compatible programs. While this is a reserved authority to NRC, staff believes, as demonstrated through the current Integrated Materials Performance Evaluation Program (IMPEP) process, that a continued collaborative IMPEP program administered by NRC within a NMP framework is possible and will fulfill that statutory responsibility.

NRC staff, the OAS Executive Board, and State members of the CRCPD Board of Directors have coordinated in the development of five pilot projects to provide further experience with the Alliance Option. Such experience will help provide insight into whether an informal coalition of programs, as envisioned in the Alliance Option, can be effectively implemented and whether individual State programs are willing and able to provide resources for such a program.

NRC staff, the OAS Executive Board, and the CRCPD Board discussed the need to “test” assumptions reflected in the Alliance Option. One area needing confirmation relates to providing the Agreement States with greater assurance that NRC is prepared to continue to evolve and operate in a different structure; a NMP structure where the States have greater technical expertise in certain materials program areas, where the NRC and Agreement States share in establishment of priorities for the NMP, and where the States assume and carry out greater responsibility for the development and maintenance of NMP products. NRC must demonstrate

willingness to operate in a NMP framework and use regulatory products which may have been developed by a single State, a group of States, or a working group comprised mostly of State staff.

A second area needing confirmation relates to providing the NRC with greater assurance that the Agreement States are willing and able to assume the necessary responsibilities and to fulfill those responsibilities in a manner which will meet both NRC and Agreement State program needs. The States need to demonstrate: that they are willing to take on additional responsibility; that they have the ability and resources to produce timely products which meet both NRC and Agreement States program needs; and that the products can be applied in either NRC or Agreement State materials programs without the need for major change. States need to demonstrate through their actions that either individual Agreement States, OAS, CRCPD, or a combination of these organizations could take on additional responsibilities under a NMP structure and produce products for the program on schedule.

Without Agreement State assumption of greater responsibility, and an associated decrease in resource burden for NRC, NRC will not be able to effectively meet demands of the NMP without a significant fee burden on the decreasing number of NRC licensees unless off fee base funding relief is provided to support a NMP. The States need to do more given their greater share of the licensee population. But, NRC at the same time must be willing to accept work products that would be developed principally by States and to share with the Agreement States the establishment of priorities for work supporting the NMP.

Pilot Projects

NRC staff, the OAS Executive Board, and State members of the CRCPD Board of Directors collaborated in the identification of five pilot projects which can be readily implemented, and which will help provide additional information on how the States and NRC might operate within an Alliance type program structure. The State members of the CRCPD Board of Directors and the OAS Executive Board agree with the five pilots. The pilots can be implemented without significant resource impacts on NRC programs, and will be initiated within 2 months and completed within a reasonable time frame (i.e., 12-18 months). In addition, eight key objectives have been developed that will be applied as success measures to help evaluate the pilot projects. Staff will provide the Commission a status report in 12 months and a subsequent final report on the results of the pilot projects including an analysis of resource expenditures (and savings, if realized) from the pilots. Staff will apply the success measures identified below as the basis for the analysis. Each Pilot Project description includes the views of both the NRC staff and the collective views of the OAS Executive Board and State members of the CRCPD Board of Directors.

1. Success Measures:

Key objectives of the pilot projects which will be used to measure success follow:

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.

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.
3. Provide demonstration that States can assume and carry out greater responsibility for the development and maintenance of products under a NMP.
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.
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.
6. Provide demonstration that NRC can operate in a NMP framework and will be able to use products which may have been developed by a single State or group of States without the need for major change.
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.
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.

2. Pilot Project Descriptions:

Project 1. Under this Pilot, NRC staff would look for opportunities to involve Agreement States in the establishment of priorities for development of materials policy, rulemaking, and guidance products in the materials and waste arenas. Staff would identify opportunities to invite early State representation in a meeting or meetings where materials program needs are discussed and where activities and products needed in the materials and waste arenas are discussed and prioritized. Prior to the meeting, the States would utilize their own process to identify a collective State position on work product needs and priorities of the States for presentation and discussion at the meeting. One product of the meeting(s) could be a multi-year plan describing the major work products needed and commitments on the organization which would assume lead responsibility for development of the products.

This Pilot could demonstrate NRC's willingness to involve the States to ensure that State needs are known and considered along with those identified by NRC staff in the establishment of national priorities and in the identification of major materials program work. It could also demonstrate the States ability to establish program goals from a national perspective. Such State participation could also serve to identify specific program needs and activities where the States would take the lead; areas where the States could possibly assume lead responsibility for the development of specific work products needed in the materials program. If States were to

take responsibility for certain work products, NRC could shed work in those areas leading to resource savings. State participation could also identify areas where the NRC and States would work collectively through NRC/Agreement State working groups to develop a product to address a need, reducing overall NRC resources in that area. Such work could be done by an individual State, a group of States, the CRCPD, or through use of an NRC/State working group.

NRC staff believes this Pilot appears essential to help establish a process and understanding on how NRC and Agreement States can collaborate in the establishment of work products and priorities for products needed in the materials program. The meeting(s) envisioned for this Pilot would also serve as the mechanism to further define and develop implementing plans for each of the other four pilot projects including details of NRC and individual Agreement State program commitments and resources needed to carry out the pilot projects. The goal of the meeting(s) would be to develop a better understanding of the collective NRC and Agreement State regulatory product needs and agreement on how that work would be accomplished through either individual or shared program responsibility.

The State members of the CRCPD Board of Directors and the OAS Executive Board believe this Pilot is significant as a means of establishing a process and understanding of how NRC and States can collaborate in the identification of regulatory priorities and corresponding work products. It is significant in establishing the collaborative spirit of the Alliance concept. It can also serve to develop the implementing plan for the other four pilot projects.

Project 2. NRC accepts Agreement State/CRCPD assumption of lead responsibility for administration of a national radiographer certification program, including development, approval and administration of tests. The CRCPD already has an established Committee on industrial radiography and NRC has actively coordinated with the Committee on review of radiography certification programs.

NRC staff believe this Pilot is an area where the States and CRCPD have already established programs and have demonstrated leadership in the development and operation of the radiographer certification program. This is an area where the States, working through the CRCPD, could take the lead in the development and operation of a national radiographer certification program which NRC and Agreement States could apply in support of their individual licensing programs. The OAS Executive Board and State members of the CRCPD Board of Directors believe the States and CRCPD have already demonstrated leadership and established programs associated with this Pilot. This effort is already viewed as a national radiographer certification program. The pilot project should demonstrate the States and CRCPD becoming the approval body for all certifying entities.

Project 3. Agreement States participate in a joint process with the NRC to evaluate the collective set of Agreement State and NRC licensee events for possible generic implications and possible additional regulatory action. Agreement States agree to provide staff and to support a joint NRC/Agreement State evaluation of the collective set of events. Such a collective evaluation could be performed by a standing committee of NRC and Agreement State staff, with opportunity for staff rotation.

A goal of this Pilot will also be to develop criteria that would enable Agreement States to assume a lead role for the evaluation of events occurring in individual Agreement States for generic implications and regulatory action.

NRC staff believes this Pilot will provide opportunity for the Agreement States and NRC to participate in the review of events nationally for generic issues and can lead to greater Agreement State assumption of responsibility to review events for issues and possible regulatory action. The OAS Executive Board and the State members of the CRCPD Board of Directors believe this Pilot, in a two-phased approach, will demonstrate a truer national evaluation of events for generic implications and issues.

Project 4. Under this Pilot, an Agreement State assumes responsibility for development of licensing and inspection guidance for a new use of material, or a new modality, not previously reviewed and approved. The Pilot would demonstrate that the regulatory agency having jurisdiction over the manufacturer of a new device or product would develop, in coordination with NRC and other Agreement States, the licensing and inspection guidance which reviewers should apply in reviewing applications, issuing licenses, and conducting inspections for the new product or technology. The regulatory products resulting from the review could consist of a Sealed Source and Device (SS&D) registry sheet, if appropriate, a set of licensing guidance which all programs could use in the review of applications for use of the new device or product, and revised inspection guidance. The development of licensing and inspection guidance along with the SS&D registration for new products or modalities by a single regulatory program would provide efficiency gains for all programs in eliminating the need for each program to independently develop the supporting implementing guidance.

NRC staff believes this Pilot reflects a pilot where the Agreement States could demonstrate their experience, expertise, and ability to produce a product on schedule which meets both NRC and Agreement States needs. The OAS Executive Board and State members of the CRCPD Board of Directors believe this Pilot can demonstrate how "Centers of Expertise" can be used to develop work products, as reflected in the Alliance concept.

Project 5. NRC and the Agreement States work cooperatively through a joint working group to address implementation of specific Phase II recommendations, including ongoing work of the existing working group to draft and pilot test revisions to Inspection Manual Chapter (IMC) 2800. Under this project, the working group will continue with current activities to pilot test and evaluate new inspection procedures, to prepare a final set of revised inspection procedures based on the Pilot, and to identify and feedback lessons learned and experience of the project to help understand the ability to realize efficiency gains through changes such as those proposed for IMC 2800.

NRC staff, the OAS Executive Board and State members of the CRCPD Board of Directors agree this Pilot reflects an activity already underway which can and should be evaluated as a pilot.

Additional View of the State Members of the CRCPD Board of Directors

The CRCPD Board notes that in the NRC staff's discussion of the Pilots, only Agreement States are referenced. The NMP Working Group recommendation of the Alliance Option did not limit involvement to only Agreement States. The CRCPD Board recommends that NRC remain open to the possibility of non-Agreement States participating in the recommended pilot

projects. NRC staff notes that NRC has previously requested, on a case-by-case basis, non-Agreement State staff participation, usually through the CRCPD, on a working group or at a stakeholder meeting and would plan to continue to do so in the future, when appropriate.

RESOURCES:

NRC Resource Discussion

Specific resource estimates for each pilot will be determined based on development of the individual implementation plans. Resources currently identified in the budget for NRC/State working group activities are expected to be adequate to cover NRC resource needs for the pilots. Consistent with the proposed Alliance Option, NRC costs for the pilot projects will include travel and per diem for State staff participation. These costs are included within STP's current invitational travel budget. Staff will seek ways to keep such expenses to a minimum through the use of tele- and video-conferencing, where possible.

Although the pilot projects will not result in any short term resource savings for NRC, staff is proceeding with the pilots to gain further experience in use of a collaborative program with the States. This experience, focused on a limited number of specific projects, can help demonstrate whether an effective program can be developed, and can help improve understanding of whether the program can provide resource savings for NRC in the future through leveraging of work completed by the States.

OAS Board and CRCPD Board Input on Resources

It is imperative that all parties involved in these pilot projects understand the varying State resources, including States' abilities to participate at varying levels of involvement. Resource limitations such as staffing levels vs. workload, travel monies, and the ability to travel out-of-state, may all impact the resources committed by the States to the pilot projects. Some States may be able to commit staff to travel to meetings to develop work products. Others may not be able to travel, but can dedicate some staff time to "electronic" meetings and collectively developing a work product. Other States may only be able to commit staff time to provide review of draft work products, while still others may not be able to devote any staff time, depending upon the regulatory issue. Therefore, it will be essential to develop an implementation plan for each project. The implementation plans should specify as best possible the expected end product, deadlines, time commitment necessary, travel required, and the tele-conference/video-conference time required. Only after these items are further outlined will States be able to prioritize their needs along with the national needs, and commit resources.

In the discussion of NRC resources, it states that the NRC would include the cost of travel and per diem expenses for State staff participation in the pilot projects. We strongly encourage this type of support as a means of facilitating implementation of the pilot projects. As noted, this is consistent with current NRC working group practice involving State staff. While travel and per diem do represent real costs, those costs must be balanced with the State staff time contribution. The NRC FTE hours saved would more than offset expenditures for travel and per diem for State staff to attend any necessary meetings associated with the pilot projects.

Many States are currently facing fiscal issues and pressures that will have an impact on the degree of participation in the pilot projects. However, we view this as a cyclical occurrence that will fluctuate with the national economy and with each State's economy. This will need to be understood by all parties involved in the process. It is envisioned that the collaborative Alliance process will account for different parties to take the lead at different times when resources and priorities dictate, and that those lead parties will change over time.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer (OCFO) has reviewed this paper for resource implications and has no objections. OCFO did not review the comments of the OAS Executive Board and the State members of the CRCPD Board of Directors. This paper has also been coordinated with the OAS Executive Board and State members of the CRCPD Board of Directors.

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