

# National Materials Program

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## Options and Recommendations



**Final Report of the Working Group**  
**SECY 99-250**

**Volume I**  
**May 2001**

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**Final Report of the Working Group**

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# National Materials Program Working Group Report

examines

- *impacts of increasing number of Agreement States*
- *six options for a National Materials Program structure*

and

- *the following six issues as specified in SECY-99-250*

**Development of an overall program mission statement with defined top level goals and objectives.**

**Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc.**

**Delineation of the scope of activities to be covered by the program and the need for statutory changes at both state and federal levels.**

**Establishment of formal program coordination mechanisms.**

**Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.**

**Provision/budgeting of resources at both state and federal levels.**

# National Materials Program

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## Acknowledgments

*First, we wish to thank the families of the Working Group members for their support. Without it this project would not have been successful. This project required a lot of travel and a lot of your family member's personal time, late at night and on weekends, away from you. We truly appreciate your sacrifice and the many special arrangements you made to allow us to complete this report.*

*We also thank the members of the Working Group for their vision, insight and dedication to this project. From the very beginning, you recognized the scale and importance of the project and set forth to complete it on time. You gave your best and characteristically, our meetings were full of enthusiasm and synergy. The Co-Chairs thank you for your effort and contribution.*

\*\*\*

*The National Materials Program Working Group would like to thank the states of Colorado, Georgia, Illinois, Massachusetts and Texas, and the Nuclear Regulatory Commission's (NRC's) Office of State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Office of General Council, Office of Chief Financial Officer, and Regions I and IV for allowing their staff the time to participate in this important effort. We also thank the NRC for the funding to support travel of the working group members and especially Brenda Usilton, who processed the travel vouchers.*

*The states of Colorado, Georgia, Illinois, South Carolina, NRC Regions III and IV, and NRC Headquarters staff hosted our meetings. Because this was a large Working Group with a complex task, our meeting needs were often complicated. Your hosting of our meetings was a big help. Your contributions made our meetings successful.*

*We thank the Conference of Radiation Control Program Directors, Inc., the Organization of Agreement States, and the New England Radiological Health Committee for providing time during your annual meetings for the Working Group to discuss its efforts and obtain comments and suggestions. These organizations recognize the importance of the role of the states in a National Materials Program and have been very supportive of the Working Group's efforts.*

## **Acknowledgments - continued**

*We sincerely appreciate the suggestions and comments we received from licensees, consultants, non-government organizations, states, co-workers and other stakeholders during tabletop exercises, public meetings, and outreach sessions. We appreciate the work done by the Health Physics Society in providing information about the project to its members via their Newsletter and at local Health Physics Society chapter meetings.*

*The Working Group would like to thank the Steering Committee for its comments and guidance. We have done our best to incorporate your perspective on the project.*

*Bob Moody, Sherri Miotla, and Cathy Colleli of NRC's Inspector General's office receive our thanks for their objective review of the working group's process, preliminary work and draft report. Your concise comments were especially valuable and improved the quality of our report.*

*We are especially blessed to have Margaret Henderson, Texas Department of Health, as our editor. Margaret took our draft text and turned it into a beautiful, easy to read, document. She has, thanks to her special talents, made us "look good." Thanks, Margaret!*

*A special note of thanks also goes to Jim Drinnon, Georgia, for his assistance in using the relative value decision matrix, and to Ann Frescura of Illinois for the Working Group logo design.*

\* \* \* \* \*

**Kathy Allen, Co-Chair**

**Jim Myers, Co-Chair**

## **Executive Summary**

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In November 1999, NRC Commissioners 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 "National Materials Program."

Currently, 32 Agreement States regulate approximately 16,500 radioactive materials licensees and NRC regulates approximately 5,000 licensees. As the number of Agreement States continues to increase, the number of licensees under NRC jurisdiction will continue to decrease. This trend has resulted in:

- shifting expertise from NRC to Agreement States
- decreasing numbers of licensees to support NRC's infrastructure
- increasing likelihood that new technologies will emerge in an Agreement State, rather than in an area under NRC jurisdiction

The National Materials Program Working Group, consisting of six representatives from states and six NRC representatives and an NRC advisor, first met in early 2000. The Steering Committee consisted of nine senior NRC managers and two Agreement State program directors.

Because there is no clear definition of a "National Materials Program," the Working Group defined the attributes of a national program. SECY-99-250 directed the Working Group to address the following six issues:

1. Development of an overall program mission statement with defined top level goals and objectives.
2. Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including Organization of Agreement States and Conference of Radiation Control Program Directors, Inc.
3. Delineation of the scope of activities to be covered by the program and the need for statutory changes at both state and federal levels.
4. Establishment of formal program coordination mechanisms.
5. Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.
6. Provision/budgeting of resources at both state and federal levels.

## **Executive Summary-cont'd**

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The Working Group defined its mission to “develop options for the Commission’s consideration for creating a National Materials Program that will implement the following philosophy:

**To create a true partnership of the NRC and the States that will ensure protection of public health and safety and the environment...”**

The Working Group’s mission and philosophy is consistent with NRC’s Strategic Goals and Objectives.

The Working Group then identified the program elements necessary for a National Materials Program. These included, but were not limited to, elements such as licensing and inspection programs, rule and guidance development, and mechanisms for communicating with stakeholders. The current methods for implementing various program elements were defined and alternatives identified. These alternatives were evaluated against the current methods using the following objectives:

- Optimize resources of federal, state, professional, and industrial organizations
- Account for individual agency needs and abilities
- Promote consensus on regulatory priorities
- Promote consistent exchange of information
- Harmonize regulatory approaches
- Recognize state and federal needs for flexibility

Once basic program elements were identified, the Working Group developed options for a National Materials Program. After defining the current national regulatory program, five other options were developed and discussed. Options ranged from allowing all states to independently regulate all radioactive materials without federal oversight to having only one regulatory entity with jurisdiction over all radioactive material in the United States.

The Working Group sought input from stakeholders at several meetings, and conducted a tabletop exercise at the October 2000 Organization of Agreement States meeting to test a consensus-based national program. One of the comments repeated at various meetings with stakeholders reflected the need to have a leadership presence at the national level.

## **Executive Summary-cont'd**

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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 National Materials Program Working Group recommends that the Commission adopt the Alliance Option, a cooperative, consensus process for a National Materials Program. The Alliance serves as a basis for achieving NRC's current strategic goals and objectives, as well as the future goals and objectives of a National Materials Program. The Alliance offers the prospect of leveraging NRC's program by joining in a continuing collaborative process with other regulators. The process would jointly establish national priorities and agendas, share resources, and develop common regulatory products. Implementation of the Alliance Option will assist NRC by continuing its presence in a National Materials Program, as its share of licensees nationwide decreases.

An Implementation Plan should also be developed and used to ensure that the Commission's directions regarding a National Materials Program are fully enacted.

In addition to the structure for a National Materials Program, the Working Group identified several enhancements that could be used with or without changes to the national program. Regardless of which option the Commission selects, NRC should encourage the use of Centers of Expertise to supplement its abilities and should continue its role in maintaining an information infrastructure. In addition, NRC should create a Standing Compatibility Committee to ensure consistency of compatibility determinations for all rules. Finally, NRC should seek authority to regulate discrete naturally-occurring or accelerator produced radioactive material in order to ensure national consistency in the regulation of all radioactive material.

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## **SECTION I**

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**In Section I, the Working Group considers the impact of the increasing number of Agreement States. The Group examines the current materials program and the relationships between NRC and states. The section presents the history, current status, and future challenges of the program. Current models and voluntary organizations are examined with specific details about the contributions of the Conference of Radiation Control Program Directors and Organization of Agreement States. The impact of the increasing number of Agreement States on resources of NRC and Agreement States is estimated.**

## Relationships Between NRC and States History, Current Status, and Future Challenges

*History, current models, future challenges, and relationships between NRC and states were considered in developing options for a National Materials Program.*

**In 1959, Section 274 was added to the Atomic Energy Act**

Section 274(g). of the Atomic Energy Act, authorizes and directs the Nuclear Regulatory Commission... "to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible."

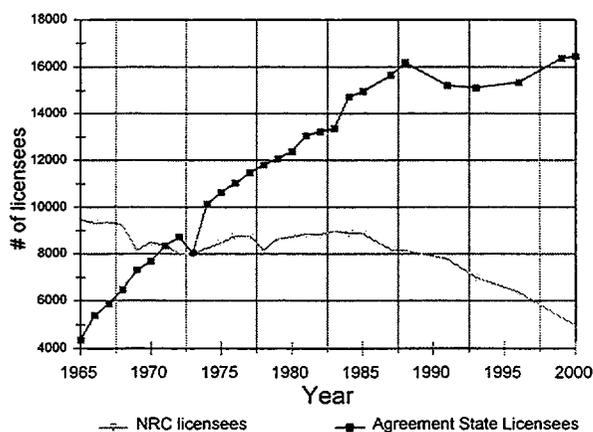
This was the culmination of early efforts by the U.S. Congress, states, federal officials, and other organizations to coordinate the regulation of radiation.

### History

The tradition of cooperative regulation of radioactive materials originated over 40 years ago. Relationships and cooperation between the Atomic Energy Commission (AEC) and the states were formally defined by federal statute when the Atomic Energy Act (AEA) was amended with Section 274. These relationships have evolved over time.

Currently, 32 states have signed formal agreements with the Nuclear Regulatory Commission (NRC) or its predecessor, the AEC, and regulate radioactive materials as "Agreement States." The historical progression of state and federal relationships is shown on page 1.3. Figure 1.1 shows the change in the number of NRC and Agreement State licenses over time.

**Figure 1.1-Active Materials Licensees**



## Relationships of Regulatory Programs

*NRC and states have a long history of cooperation.*

- 
- 1950s** Relationships and cooperation began between AEC and the states. AEC recognized the need to consult with the states on emerging radiation safety issues. A few states were regulating some radioactive materials prior to the addition of Section 274 to the AEA.
- 1955** AEC Director of Operations formed an advisory committee of state officials to advise AEC regarding federal/state relations. The committee's work continued for a period of time after enactment of Section 274 and the committee was later disbanded in the mid to late 1960s.
- 1959** Section 274 was added to the AEA. The purpose of Section 274 was, in part:
1. to recognize the interests of the states in the peaceful uses of atomic energy
  2. to clarify the respective responsibilities of the states and the Commission under AEA with respect to the regulation of byproduct, source, and special nuclear materials
  3. to recognize the need for and establish programs for cooperation between the states and the Commission
  4. to promote an orderly regulatory pattern between the states and the Commission
  5. to provide a mechanism for discontinuance of certain Commission authority and state assumption of authority for activities involving byproduct, source, and specified quantities of special nuclear material
  6. to recognize that additional legislation may be desirable as the states improve their capabilities to effectively regulate such materials
  7. to authorize and direct the Commission to cooperate with the states in the formulation of standards for protection against radiation hazards
- 1962** Kentucky became the first Agreement State and assumed responsibility for regulating AEA material (byproduct, source and specified quantities of special nuclear material) within its borders.
- 1971** The number of Agreement State licensees exceeded the number of AEC licensees.
- 1975** The Nuclear Regulatory Commission was formed.
- 2000** The number of Agreement States grew to 32.

## National Materials Program - Current Approaches

*Multiple governmental systems perform regulatory functions for the academic, medical, and industrial use of radioactive materials.*

### **Multiple approaches....**

- NRC
- Agreement States
- Non-Agreement States
- Other Regulatory Agencies

Through combined authority and resources, this network of organizations addresses the regulation of:

1. radioactive material, including AEA materials, NARM (naturally-occurring or accelerator produced material)
2. radiation produced by machines (x-ray)
3. nonionizing radiation

***No national program comprehensively covers the full spectrum of radiation which is regulated for the purposes of health and safety in the United States.***

### **Current Status**

Governmental systems that perform regulatory functions in the United States reside in federal and state programs. They are:

1. **NRC** - The federal agency that regulates use of byproduct, source, and special nuclear material in non-Agreement States and U.S. territories, by federal entities, and in areas of exclusive federal jurisdiction.
2. **Agreement States** - State governments that have signed agreements with NRC to regulate AEA material within their respective jurisdictions, with exception of activities exclusive to NRC or those specified in their agreements. The Agreement States also regulate NARM and machine-produced radiation (accelerators and x-ray equipment).
3. **Non-Agreement States** - State governments that have not signed agreements with NRC, but can regulate NARM. Most non-Agreement States also regulate machine-produced radiation.
4. **Other Regulatory Agencies** - The Department of Energy has its own set of standards for sites under its jurisdiction. The Environmental Protection Agency has air and water emissions standards that may differ from NRC rules. The Occupational Safety and Health Administration and the Department of Transportation both have requirements for handling, using, or transporting radioactive material. The Food and Drug Administration regulates mammography and evaluates drugs and devices used in medicine.

## Comparison of Three Approaches

*NRC, Agreement States, and non-Agreement States have different approaches and responsibilities.*

### Agreement States

States promulgate rules, policies, and procedures to implement and manage their programs, respond to incidents and events, issue licenses, and conduct inspections.

Most Agreement States conduct sealed source and device evaluations that are documented in NRC's database; however, a few Agreement States have chosen not to perform these evaluations.

Agreement States must maintain programs that are adequate to protect public health and safety.

Byproduct, source, and special nuclear material rules are required to be compatible with NRC rules, as determined during NRC's rulemaking process.

Some Agreement State and NRC program functions must be compatible.

### Non-Agreement States

Non-Agreement States can regulate NARM and machine-produced radiation as required by state statutes.

### Nuclear Regulatory Commission

NRC exercises regulatory jurisdiction over AEA materials in non-Agreement States. In Agreement States, NRC retains authority over federal agencies, production and utilization facilities, export and import activities, disposal in the oceans, high level waste handling and disposal, transfer of materials to persons exempt from licensing (consumer products), large quantities of special nuclear material, off-shore waters, certain aspects of mill tailings management, and certain activities conducted within some Agreement States, as specified in the respective agreements. NRC also maintains an oversight function for determining adequacy and compatibility of Agreement State programs.

NRC interfaces with federal agencies and Congress about the nationwide materials program.

NRC maintains the lead in establishing priorities and policy for developing rules and standards for the use of AEA material for the nation. NRC responds to incidents and events, issues licenses, conducts sealed source and device evaluations, and conducts inspections of its licensees.

NRC also reviews certain transportation packaging, issues exempt distribution licenses, and maintains national databases for:

- sealed source and device certificates issued by NRC and states
- incidents and events reported by NRC and Agreement State licensees
- certificates of compliance issued for transportation packages

NRC is the primary contact for most incidents and events that cross regional and Agreement State boundaries, and also provides technical assistance to states for event response when needed.

## Coordinating Organizations

*Conference of Radiation Control Program Directors, Inc., and Organization of Agreement States facilitate coordination of radiation control activities.*

The Conference of Radiation Control Program Directors, Inc. (CRCPD), is a voluntary professional organization whose primary membership is made up of individuals in state and local government who regulate the use of radiation sources. Other members include individuals with an interest in radiation protection.



SSRCRs help to establish consistency in radiation rules. Stakeholders have stated that variations in rules between states leads to confusion for the regulated community, particularly for those licensees who have operations in several Agreement and non-Agreement States.

CRCPD was established in 1968 and its membership is open to representatives from all state, local, and federal governments who regulate and control the use of sources of radiation. Individuals, regardless of employer affiliation, who have expressed an interest in radiation protection may join. CRCPD also has international members.

CRCPD is directed by a seven-member Board of Directors, whose membership is elected from state radiation control personnel. Day-to-day operations of the organization are administered by the Executive Director and staff who are employees of the organization.

CRCPD sponsors committees that write and publish Suggested State Regulations for Control of Radiation (SSRCRs), making them available for use by the states. Other CRCPD committees research technical issues, develop guidance documents, and prepare background information for SSRCR committees. A CRCPD committee also reviews applications from states requesting Licensing State status.

SSRCRs provide a tool to aid states in development of rules that are consistent across the nation. Both Agreement and non-Agreement States use SSRCRs published by CRCPD as a guide to writing state rules. These suggested rules include NRC's compatibility determinations. NRC participates with states in the development of SSRCRs for radioactive materials. This effort is consistent with purposes specified in Section 274 of the AEA. Despite the compatibility requirements determined by NRC and the efforts of CRCPD to establish consistency in radiation protection standards nationwide, differences exist due to varying state laws. These differences have **not** led to a decrease in public health and safety.

## Coordinating Organizations - cont'd

*Conference of Radiation Control Program Directors, Inc., and Organization of Agreement States facilitate coordination of radiation control activities.*

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**Licensing States**  
are those states  
that have been  
designated by the  
CRCPD pursuant  
to criteria found in  
Publication 94-8  
"CRCPD  
Recognition of  
Licensing States  
for the Regulation  
and Control of  
NARM."

### Licensing State Status

CRCPD may confer Licensing State status to states. To become a Licensing State, a state promulgates rules and procedures for control of radiation hazards for non-AEA materials that are similar to those rules and procedures used by NRC, other Agreement States, or other Licensing States. Licensing State status assures other states that licensees and/or sources and devices are subject to equivalent licensing practices with respect to discrete sources of NARM, including an adequate quality control program. Vendors in a Licensing State may be granted reciprocal recognition of their license or acceptance of their product. Upon the recommendation of the CRCPD Licensing State committee, CRCPD confers Licensing State status.

Currently, no non-Agreement States are recognized as Licensing States. This creates a potential problem because some non-Agreement States allow companies to produce and distribute NARM products to users in other states. In those situations, there is no guarantee that quality assurance programs that control the manufacturing and distribution of such products have been approved by any licensing authority.

## Coordinating Organizations - cont'd

*Conference of Radiation Control Program Directors, Inc., and Organization of Agreement States facilitate coordination of radiation control activities.*

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Organization of Agreement States

**OAS's primary purpose is to provide a forum for Agreement States to work together and with NRC.**

### Organization of Agreement States (OAS)

OAS is a voluntary organization of individuals from Agreement States. Its primary purpose is to provide a mechanism for Agreement States to work with each other and with NRC on regulatory issues associated with the agreements.

The AEC and Agreement States began holding annual meetings in 1964. In 1971, when states chose to meet separately from AEC for about half a day during these meetings, OAS began to develop. States elected a chairman whose main tasks were to organize the state portion of the meeting and send a letter with recommendations to the Director of the Office of State Programs. The current Executive Board includes the chair, chair-elect, past chair, secretary and secretary-elect. These positions are held by Agreement State representatives.

Prior to the 1990s, NRC set the agenda for these meetings and funded travel costs for Agreement State representatives' attendance. During the 1990s, NRC funding ceased and Agreement States began funding their attendance at the meetings. This change also resulted in the Agreement States taking a more active role in determining the meeting agendas. Today, OAS determines the agenda with input from NRC. The OAS Executive Board and NRC have monthly conference calls during which participants discuss the status of activities of interest. In addition, the OAS Executive Board and the CRCPD Chair brief the Commission annually.

## Future Challenges for a National Materials Program

*NRC and Agreement States must create a structure to accommodate shifting licensee populations and regulatory expertise.*

**32 Agreement States are responsible for 75% of the total licensees and by FY 2003 that number is expected to increase to over 80%.**

The continuing shift in licensee population has implications for both NRC and Agreement State programs.

### Changing Status of Agreement State and NRC Programs

At the present time, NRC exercises regulatory responsibility over approximately 5,000 materials licensees, and the 32 Agreement States regulate approximately 16,500 materials licensees. NRC staff expects three additional states to become Agreement States by FY 2003 and estimates that the number of NRC licensees will drop to approximately 4,000. At that time, the Agreement States will be regulating about 17,500 licenses. This continuing shift in licensee population, both in number and type of radioactive material user, has the following implications:

- ✓ the shift in expertise for certain types of licenses from NRC to the states could affect NRC's ability to effectively regulate that technology
- ✓ NRC may find it more difficult to maintain a regulatory infrastructure with a decreasing number of licensees
- ✓ the decreasing number of NRC licensees increases the licensee fee burden
- ✓ increased state experience in regulating AEA and non-AEA sources of radiation is shifting expertise to the Agreement States
- ✓ new technologies are more likely to emerge in an Agreement State than in an NRC-regulated jurisdiction

To develop and maintain the infrastructure of rules and supporting guidance, NRC will need to use a process that reflects this shift.

## Resources Budgeted for Materials Regulation

*Assumptions were necessary to compare NRC and state resources.*

### Comparison:

**FTE per 100  
specific  
licenses**

**States -  
2.0 to 3.2 FTE**

**NRC - 3.0 FTE**

State and NRC resources are compared in terms of FTE per 100 licensees. Resource data in Figure 1.2 on the following page shows a range of program sizes and are reported in:

- full time equivalent positions (FTE)
- numbers of specific licensees

### NRC and Agreement State Resources

Resources currently budgeted by states and NRC in materials programs were compared using NRC FY 2001 materials budgeted resources. Differences in how NRC and the states prepare and report on budget items, as well as the scope of the programs, required the Working Group to make assumptions in order to compare the number of full time equivalent (FTE) NRC and state positions per 100 licenses.

### Assumption: Scope of Programs

Differences in the scope of programs have an impact on resources. Certain assumptions were made in order to compare similar efforts. For example, low-level waste and uranium recovery resources were omitted because they are not common to all states. NRC Site Decommissioning Management Plan resources were omitted because the states do not individually have the legacy of these sites. Also, NRC maintenance of the national infrastructure was not included in the comparison.

The Working Group considered separating resources associated with the regulation of discrete NARM from the materials license totals for the individual states. However, it decided to include NARM totals for these reasons:

1. An infrastructure already exists in terms of licensing/inspection. Therefore, the Working Group concluded that, outside of start-up costs for NRC, regulation of NARM was not a significant resource issue.
2. Agreement States do not differentiate between AEA materials and NARM when licensing and inspecting. The resource implications for licenses with both NARM and AEA materials would be insignificant because the radiological hazards associated are similar.

NOTE: State personnel from Agreement and non-Agreement States indicated that most licensees have both AEA material and NARM. A majority of licensees with only NARM appears to be associated with sealed sources of low activity. For example, New Jersey, a non-Agreement State, has 382 NARM licensees. Approximately 230 of these licensees also have NRC licenses for AEA material. Approximately 100 of the remaining NARM-only licenses authorize the use of sealed sources in x-ray fluorescence and lead paint analyzers that are of minor radiological significance. The remaining approximately 50 licensees would require regulatory attention similar to that for AEA material licensees.

## Reference Table

**Figure 1.2 - 2001 Resource Data**

State/NRC	Specific licenses*	FTE	FTE/100 Specific Licenses
Rhode Island	63	1.9	3.0
Maine	129	2.75	2.1
Colorado	312	6.2	2.0
Georgia	481	11	2.3
Massachusetts	524	17	3.2
Illinois	740	20	2.7
Texas	1480	42	2.8
NRC	5000	149	3.0

\* State numbers include specific licenses for NARM.

Notes:

1. Illinois, Colorado, Texas, and NRC resources are approximate and do not include 11.e.(2) byproduct material or low-level radioactive waste programs.
2. Georgia and Illinois resources do not include environmental monitoring and emergency response program costs.
3. Resources do not include corporate overhead (e.g., indirect FTE).

Note that the range in FTE/100 licenses for states and NRC reflect the emphasis or challenges unique to a program, the distribution in the type of materials licensees, and each agency's budgeting process. For example, the Massachusetts program has several staff members assigned to the evaluation of sealed sources and devices due to the concentration of manufacturers in the Commonwealth.

## Effects of an Increasing Number of Agreement States on NRC Resources

*Currently, NRC must maintain a national materials infrastructure regardless of the number of NRC licensees.*

As the number of Agreement States increases, the NRC license base decreases. To evaluate the impact of this change, the Working Group used the NRC FY 2001 budget in the Materials Arena. Because the NRC budget is not organized in terms of those program elements subject to agreements under Section 274, the Working Group eliminated those activities that are not impacted by the agreements (fuel cycle activities and support for spent nuclear fuel) and added resources from the 2001 budget in areas which were determined to be common to NRC and Agreement State materials programs (low-level waste and uranium recovery activities). The Working Group also included resources to maintain the framework for materials regulation and those NRC efforts to support the materials program. The additions are represented in the left column, "Analysis of Impacts Includes:" below.

In order to more accurately predict the manner in which NRC resources would vary under conditions of a changing licensee base, the Working Group divided the NRC resources into two groups, those which can reasonably be expected to change in a linear fashion with the number of licensees and those whose change is more complicated. These directly variable and indirectly variable resources are defined below. This concept was also used when evaluating the resource implications of options in Section III.

### Analysis of Impacts Includes:

- decommissioning
- low-level waste
- uranium recovery
- direct support of materials activities, including
  - legal
  - enforcement
  - event assessment
  - investigations
  - research
  - state and tribal programs
- indirect support of materials activities, including
  - financial
  - administrative
  - information technology infrastructure
  - personnel
  - physical plant

### Directly Variable Resources and Indirectly Variable Resources

As used in evaluation, *directly variable resources* are those NRC resources that change directly as the number of NRC licensees change (e.g., FTE dedicated to licensing, inspection, etc.).

*Indirectly variable resources* are those NRC resources that are dependent on program or policy *decisions* and are not necessarily directly affected by the number of NRC licensees. Indirectly variable resources also represent regulatory activities particular to NRC's oversight role and implementation of the current materials program.

When both directly and indirectly variable resources are combined, NRC has a total resource of 336 FTE in FY 2001 or 6.7 FTE per 100 licensees. Projected for FY 2004, the total FTE will be 316 or 7.9 per 100 licensees.

Figures 1.3 and 1.4 provide a summary of resources and impacts data.

## Reference Tables

Figure 1.3 depicts the current NRC resource structure. Figure 1.4 depicts the projected change in NRC resources for directly and indirectly variable resources under the existing materials program if NRC policies and program activities implementing those policies do not change as the anticipated number of NRC licensees decreases. Decreases in NRC licensees are predicted to result from the addition of three new Agreement States by FY 2004.

**Figure 1.3 - Current NRC Resource Structure**

Activity	Directly Variable FTE	Indirectly Variable FTE	Total
NMSS, Regions	71	126	197
Direct Support*	27	36	63
Agency Overhead**	0	76	76
<b>Total</b>	<b>98</b>	<b>238</b>	<b>336</b>

\* These resources include Office of State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudications.

\*\* These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support.

**Figure 1.4 - Impacts of New Agreement States on NRC Resources**

	FY 2001	FY 2004***
Number of NRC Licensees	5000	4000
Number of Agreement States	32	35
NRC Indirectly Variable resources (FTE)	238	238
NRC Directly Variable Resources (FTE)	98	78
Total NRC Resources (FTE)	336	316
FTE/100 Licensees	6.7****	7.9****

\*\*\* This data was not part of the FY 2002 budget review process, but those resources for FY 2004 will be identified by the respective offices in this year's FY 2003 budget formulation effort.

\*\*\*\* These numbers reflect total resources for the NRC that includes overhead and support resources for the materials program.

## **SECTION II**

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**In Section II, the Working Group describes the process it used to examine options for a National Materials Program. The Working Group adopted a mission, philosophy, process, and criteria for evaluating options and conducted stakeholder outreach.**

## Mission and Philosophy of the Working Group

*The Working Group adopted a mission statement that incorporates a philosophy used in evaluating options.*

**Fundamental goal:**

**Resources should be applied to a common agenda of mutually agreed-upon goals and objectives.**

Examples of duplication...

- several states have independently developed guidance for positron emission tomography
- industrial radiography rules were adopted by states, then NRC. This required many states to make conforming changes solely for compatibility purposes.

### Background

The Working Group recognized that optimizing the use of state and federal resources and accommodating differing regulatory priorities would be important for state and federal agencies working within the framework of a National Materials Program.

Currently, the materials program is largely directed by NRC, which establishes regulatory priorities for byproduct, source, and special nuclear materials. Although Agreement States enjoy a participatory arrangement with NRC in some areas (e.g., rulemaking, use of working groups, etc.) under the current process, little consideration is given to Agreement State regulatory priorities that would include, in addition to AEA materials, NARM, x-ray and accelerator generated radiation, and non-ionizing radiation hazards/sources.

Both NRC and Agreement States expend resources in an effort to accommodate differing priorities. Often, regulatory agencies resolve the same issues independently, which results in a duplication of efforts and resources. **Resources should be applied to a common agenda of mutually agreed-upon goals and objectives.** With this in mind, the Working Group developed this mission statement, "The mission is to develop options for the Commission's consideration for creating a national materials program that will implement the following philosophy:..."

### **Philosophy**

***To create a true partnership of the NRC and the States that will ensure protection of public health, safety, and the environment while:***

***optimizing resources of federal, state, professional and industrial organizations  
accounting for individual agency needs and abilities  
promoting consensus on regulatory priorities  
promoting consistent exchange of information  
harmonizing regulatory approaches  
recognizing state and federal needs for flexibility***

## Goals of the NRC

*The NRC strategic and performance goals were incorporated in criteria developed by the Working Group for evaluating potential options.*

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The Working Group incorporated NRC's strategic and performance goals as discussed below.

**Maintain safety** by establishing a regulatory oversight framework that ensures that materials licensees continue to conduct activities involving use of radioactive materials and radiation sources in a safe manner. Maintaining regulatory programs that are adequate to protect public health and safety is a priority in evaluating potential changes.

**Improve the effectiveness and efficiency of regulatory programs nationwide** by enhancing collaboration through exchange of information and resources, promoting consensus among regulatory agencies, and optimizing use of resources on a national level. A national program should seek to balance use of resources among the states and NRC and distribute the resource burden more equitably among Agreement State and NRC licensees. A national program should also account for individual or unique program needs and provide flexibility, which may be needed to expand or modify existing regulatory programs to ensure adequate oversight of unique or emerging technologies.

**Enhance public confidence** by 1) increasing consistency and predictability in regulatory approaches, while recognizing the need for flexibility among state and federal regulatory programs, and 2) improving efficiency in implementing our regulatory oversight responsibilities.

**Reduce unnecessary regulatory burden** by promoting a consistent regulatory approach nationwide which will offer efficiencies for licensees and greater predictability for stakeholders.

## Goals of the Working Group

*The Working Group identified several objectives that were used to guide its efforts in developing recommendations for a National Materials Program.*

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**1. Optimize resources of federal, state, professional, and industrial organizations**

**2. Account for individual agency needs and abilities**

**3. Promote consensus on regulatory priorities**

**4. Promote consistent exchange of information**

**5. Harmonize regulatory approaches**

**6. Recognize state and federal needs for flexibility**

### **NRC Strategic Plan, Goals and Missions of Agreement States**

The primary goal of maintaining public health and safety was consistent among NRC and state programs, although other goals identified in the various strategic plans and mission statements were not consistent throughout. They were however, generally compatible.

Based on this examination, the Working Group identified six objectives that were used to guide its efforts in evaluating options and developing recommendations for a National Materials Program. These objectives incorporate the NRC's strategic goals and are reflected in the Working Group's philosophy statement on page 2.2.

## Process to Develop and Evaluate Options

*The Working Group developed and evaluated options for a National Materials Program.*

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### **Bottom-Up Approach...**

**identify what is needed in terms of outcomes or outputs rather than immediately defining relationships or processes between NRC and states**

### **Process**

The Working Group initially examined the NRC Strategic Plan and strategic goals or mission statements established by some Agreement States. Based on this information, the Working Group decided to:

1. focus on creating a functional, rather than programmatic structure by identifying outcomes (e.g., protection of public health) and outputs (e.g., rules and guidance),
2. use a bottom-up approach by looking at basic program elements common to all radiation control programs and evaluating methods to accomplish those tasks.

### **Functional Structure**

The Working Group focused on evaluating relationships and processes that could be used by the Agreement States and NRC to achieve specific outcomes rather than initially creating new organizational structures.

### **Bottom-Up Approach**

The Working Group wanted to identify what was needed in terms of outcomes or outputs rather than immediately defining the relationships or processes required to be formed between and used by NRC and Agreement States. The Working Group first determined what a National Materials Program should do to achieve or maintain state and federal strategic goals. This method was followed rather than using a top-down approach by immediately defining a framework for a National Materials Program.

## Essential Program Elements

*The Working Group began by defining essential program elements for the National Materials Program.*

### Essential program elements

**program elements derived from...**

***Criteria for an Adequate Radiation Control Program, April 1999, and***

***NRC Management Directive 5.6, Integrated Materials Performance Evaluation Program***

The Working Group began by defining essential program elements for a National Materials Program. The elements were taken from *Criteria for an Adequate Radiation Control Program*, April 1999, CRCPD Publication 99-2, and from NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*. These defined the program elements to be evaluated.

For each program element, the Working Group identified the current methods used by Agreement States and NRC to accomplish the program element; then the group brainstormed alternative methods for accomplishing each program element.

The alternatives were initially assessed to ensure they supported the primary, common strategic goal of maintaining health and safety. If an alternative was not consistent with this primary goal, it was eliminated from further evaluation.

Alternatives for each program element are described in detail in Appendix C.

**Evaluating Options:** *Alternatives for each program element were compared to current practices, considering the six objectives of the Working Group. The alternatives were rated as being equal to, better than, or worse than the current practice. For example, each alternative for issuing materials licenses was rated with regard to optimizing resources of federal and state agencies, and professional and industrial organizations. The alternative was then rated against the existing practice for each of the remaining criteria. Based on the evaluation results, a preferred alternative, or "enhancement," was made for each program element. For some elements, the enhancement was the status quo, for some it was a new way of doing business, and for others it was a combination of alternatives.*

## Enhancements to Existing Program Elements

*The Working Group identified multiple enhancements that could be made to the existing methods for accomplishing these program elements.*

<b>Enhancements</b>	
<b>Licensing and Inspection Guidance</b>	<ul style="list-style-type: none"> <li>• NRC and Agreement States jointly develop an agenda and priorities for developing licensing and inspection guidance.</li> <li>• Use working groups to develop guidance.</li> <li>• Accept consensus standards (following review and revision, if needed).</li> <li>• Contract with other organizations to develop guidance when appropriate.</li> </ul>
<b>Performing Inspections</b>	<ul style="list-style-type: none"> <li>• Allow licensees to perform self-audits that may be accepted in lieu of inspection by NRC or an Agreement State.</li> <li>• Allow other entities to contract with NRC and Agreement States to perform inspections and report results to the appropriate regulatory agency.</li> <li>• Accept audits performed by other organizations and use these as a supplement to NRC and Agreement State inspections.</li> <li>• Use "Centers of Expertise" (see page 2.9) to perform inspections of specific technical areas.</li> </ul>
<b>Performing Licensing</b>	<ul style="list-style-type: none"> <li>• Use contracted entities to perform some license reviews or portions of reviews for specific technical areas.</li> <li>• Use Centers of Expertise to perform some license reviews or portions of reviews for specific technical areas.</li> </ul>
<b>Rule and Guidance Development</b>	<ul style="list-style-type: none"> <li>• Jointly establish agenda and priorities.</li> <li>• Use working groups or Centers of Expertise.</li> <li>• Promote development of consensus standards.</li> <li>• Contract with other organizations for technical support.</li> </ul>
<b>Training, Qualifications, and Experience Standards</b>	<ul style="list-style-type: none"> <li>• Use a clearinghouse of training ideas, resources, and opportunities designed for or employed by NRC and Agreement States.</li> <li>• Allow licensees to provide training.</li> <li>• Contract with licensees to train staff in specific technical areas.</li> <li>• Encourage a regulatory agency exchange program to develop staff in specific technical areas.</li> </ul>

## Common Themes

*After reviewing the evaluations of program elements, six common themes or attributes were identified.*

Consensus does not necessarily mean unanimity, but implies general agreement and provides an opportunity for all parties to bring issues, ideas, and concerns to the table for consideration.

**Consensus process** - Decisions concerning regulatory goals and framework should be made through a process involving both Agreement States and NRC in which general agreement is reached through a cooperative effort.

**Jointly establishing regulatory priorities** - Regulatory priorities should be set with common goals in mind. Agreement States and NRC should jointly, through a consensus process, determine regulatory priorities (research, rulemaking, guidance development, etc.). The schedule or plan for achieving those priorities and the best use of resources to accomplish those priorities should be coordinated.

**Recognition of current successes** - Agreement States and NRC have individual regulatory successes as well as successful efforts that are cooperative. Some program elements are working successfully as they now exist. Many current practices could be more successful with modifications or when enhanced with alternatives.

**Recognition of individual legal and jurisdictional issues** - Despite the need for consistency and cooperation, there will be situations in which Agreement States and NRC have unique legal or jurisdictional obligations that must be met. These specific obligations must not be impeded by a National Materials Program.

**Shared Responsibility** - Several structural options for a National Materials Program that are discussed in Section III, if fully implemented, would require more uniform resource commitment among the states and NRC.

**Sharing of Resources** - For a National Materials Program to be successful, all materials regulatory programs must participate. Participation means a commitment of resources, such as staff time or financial support.

## Sharing of Resources

*The Working Group identified several methods for sharing of resources.*

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**Reduce duplicate efforts...**

**The concepts discussed under "Sharing of Resources" will assist regulatory programs to reduce duplicative efforts and save resources.**

**Identify and use Centers of Expertise within the existing regulatory community**

Some Agreement States and NRC regions have, over time, developed considerable experience and expertise with specific uses of radioactive materials. Examples of areas of expertise include well logging, industrial radiography, positron emission tomography, and intravascular brachytherapy. Agreement States and NRC regions that have developed expertise in specific uses should be identified and used as a resource by other regulatory programs. These "*Centers of Expertise*" may change over time as others develop expertise.

**Use alternative resources where possible**

When appropriate, alternative resources should be used in conjunction with or in place of the current regulatory methods. Alternative resources can include consensus standards or enlisting the resources and cooperation of professional and industry organizations.

**Establish an information infrastructure**

A centralized "clearinghouse" of regulatory products should be established for use by Agreement States and NRC staffs. This could serve as a centralized source of information on the availability of rules, guidance documents, industry and professional standards, etc., and could facilitate dissemination of information.

## Stakeholder Outreach - NRC's Process

*The Working Group examined the current NRC stakeholder outreach process.*

As part of its process, the Working Group conducted stakeholder outreach to gain comments about the Working Group's process and possible options for a National Materials Program. The Working Group began by examining the NRC stakeholder outreach process.

### NRC's Stakeholder Outreach Process

**Regulatory decisions must be informed decisions-- it is necessary to actively seek and consider input from those persons who would be affected.**

**Input from other federal and state agencies (Environmental Protection Agency, Department of Energy, and equivalent state environmental or health agencies) charged with regulating radiation issues is sought.**

**Other stakeholders include...**

- licensees
- public
- professional organizations
- industry organizations
- other federal and state agencies with an interest in radiation issues

NRC decides when to begin rulemaking or develop policy or guidance and informs other entities that the process will begin. NRC solicits voluntary input from Agreement States and other stakeholders. Not all stakeholders choose to participate. The Commission evaluates all input appropriate in making decisions. The Commission also sets priorities and decides compatibility on the issues under development.

In addition to consulting with Agreement States and other stakeholders, the Commission uses advisory committees, such as the Advisory Committee on Nuclear Waste and the Advisory Committee on Medical Uses of Isotopes. These advisory committees are independent and autonomous from the Commission; they recommend priorities or actions that they feel the Commission should take. The Commission may accept or reject advisory committee recommendations.

The Commission contracts with various organizations for research when members believe it necessary or advisable in developing rules and guidance. This research furthers the effectiveness and efficiency of the Commission and the Agreement States in performing their regulatory functions.

The other federal and state agencies are considered stakeholders because at this time, the effort towards establishing a National Materials Program is being driven by the NRC and representatives from the state radiation regulatory agencies. It is envisioned that many of the stakeholders, i.e., other federal and state agencies and professional and industrial organizations, could become participants in the National Materials Program in the future.

## Stakeholder Outreach - Communication Plan

*The Working Group sought stakeholder involvement in evaluating the options for a National Materials Program.*

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### Outreach Methods...

- Electronic Communications
- Written Communications
- Tabletop Exercise
- Public Meeting
- Focus Groups

**A summary of the Working Group Outreach Activities is in Appendix B.**

### Stakeholder Outreach

The Working Group developed a communication plan (see Appendix B) to guide its approach in delivering its key messages and engaging the various stakeholder groups. The plan identified overall objectives, stakeholders, communication tools and opportunities, and key messages.

The Working Group provided information to various stakeholder groups on the development of the options for a National Materials Program. To obtain feedback, the Working Group used electronic and written communications, conducted counterpart and professional society meetings, tested a pilot project, met with NRC senior management, and held a public meeting.

Many stakeholders expressed satisfaction with current practices and offered suggestions that the Working Group considered in evaluating options for a National Materials Program.

## Stakeholder Outreach - Communication Plan - cont'd

*Electronic and written communications were important to the Working Group's outreach efforts.*

### **Outreach publications...**

**Internet**

**Federal Register**

**Health Physics Society Newsletter**

**CRCPD Newsletter**

### **Electronic Communications**

An important component of the Working Group's outreach efforts was the establishment of an Internet site at the beginning of the process. The Working Group used the site to provide access for stakeholders to its information during the development phase of the options for a National Materials Program. The Internet site was also used to announce all Working Group meetings. List servers focusing on radiation issues for state and federal regulators were also used to solicit input during product development and to obtain information on specific issues.

### **Written Communications**

The Working Group published notices in the *Federal Register* announcing its initial meeting in March 2000 and the public meeting in February 2001. All other meetings were posted at the Working Group's Internet site

Three articles on the National Materials Program appeared in the November 2000 *Health Physics Society Newsletter*. One of the Working Group's Co-chairs and the Chair of the Working Group Steering Committee were interviewed. The articles discussed the current regulation of radioactive material in the United States and the pros and cons of regulation by Agreement States or the NRC. These articles were available to the health physics community (regulatory and non-regulatory stakeholders) nationwide. Articles on the activities of the Working Group also appeared in the CRCPD and NRC Office of Nuclear Material Safety and Safeguards newsletters.

## Stakeholder Outreach - Opportunities

*The Working Group provided many opportunities for stakeholders to participate.*

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### **May 2000**

Presented a poster at the annual CRCPD meeting in Tampa, Florida. The poster session introduced the mission and planned activities of the Working Group to state radiation program managers and staff.

### **July 2000**

Provided information on the current status and activities at a meeting of standards development organizations.

### **July through November 2000**

Provided information on the current status and activities of the Working Group to materials staff at each of the four NRC regions and at NRC Headquarters.

### **October 2000**

Presentation and table-top exercise at the annual OAS meeting in Charleston, South Carolina.

### **November 2000**

Provided information on the current status and activities of the Working Group at the annual New England Radiological Health Committee meeting in Mystic, Connecticut. The meeting is attended by the staff and management of the six New England states and regional federal representatives from the Food and Drug Administration, Environmental Protection Agency, Federal Emergency Management Agency, NRC, and Canada.

Presented information to the regulated community in Texas at a meeting of the South Texas Chapter of the Health Physics Society. A focus group session was held after the presentation to obtain feedback on specific questions.

### **January 2001**

Presented information to the regulated community in Georgia at a meeting of the Atlanta Chapter of the Health Physics Society.

### **February 2001**

The Working Group held a public meeting in Arlington, Texas, to discuss the various options for a National Materials Program. The Working Group obtained feedback from a focus group of individuals who represented a wide spectrum of regulatory and non-regulatory stakeholders. After a presentation on the options described in Section III of this paper, the Working Group facilitated a discussion using a set of questions to obtain feedback and comments.

### **March 2001**

Presented information to the regulated community at a meeting of the New Jersey Chapter of the Health Physics Society.

### **April 2001**

Presented update on the status of the Working Group activities at the annual CRCPD meeting in Anchorage, Alaska.

## Stakeholder Outreach - Tabletop Exercise

*A tabletop exercise provided an opportunity to apply some of the National Materials Program concepts and obtain feedback.*

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### Consensus Building with Tabletop Exercise

Participants brought a list of their three top regulatory priorities over the next 7 to 28 months.

The priorities were consolidated into a single list.

The participants reached consensus on the priorities.

A group of states decided to pool their resources to work on one of the priorities.

On October 2 and 3, 2000, the Working Group held tabletop exercises for consensus building on determining the agenda for regulatory priorities at the annual OAS meeting. In addition, the Working Group gave a presentation on the current status and activities of the Working Group.

Prior to the OAS meeting, the Working Group requested that each Agreement State and NRC bring a list of their three top priorities over the next 7 to 28 months in the areas of regulations and guidance development. The priorities for each state and NRC were collected and consolidated into a single list. Copies of the consolidated list were given to each agency participant. Working Group members facilitated an exercise with the participants to reach consensus on the priorities provided by each agency.

A priority item identified by a number of states was the need for licensing guidance for positron emission tomography (PET). The Working Group considered the tabletop exercise a success because, as a result of this exercise, a group of states led by the State of Washington decided to pool their resources and develop the necessary PET licensing guide.

The interaction, discussion, and action taken on the PET licensing guidance was an important event for the Working Group in terms of stakeholder outreach because it was an opportunity to have stakeholders apply some of the National Materials Program concepts and obtain their feedback. Continuing feedback to the Working Group has been positive and development of PET guidance is ongoing.

## Stakeholder Outreach - Public Meeting

*Options for a National Materials Program were discussed during a public meeting.*

### Feedback from public meeting...

- **federal agencies should stop creating conflicting standards**
- **NRC should regulate discrete NARM**
- **Some entity should be "in charge" of a National Materials Program**
- **NRC should be willing to modify the AEA**
- **a National Materials Program should improve consistency, but allow flexibility**

A public meeting was held February 21 and 22, 2001, in Arlington, Texas, to discuss the various options for a National Materials Program and obtain feedback from a focus group of individuals representing a wide spectrum of regulatory and non-regulatory stakeholders. The stakeholders included representative from NRC, Agreement States, non-Agreement States, licensees, professional societies, environmental groups, other non-governmental organizations, and organizations representing specific categories of licensees.

For each potential National Materials Program option, the focus group participants discussed how it impacted the following:

- access to decision makers
- budget/resource implications
- legal authority
- efficiency
- uniformity/consistency
- flexibility
- comprehensiveness
- stability
- role of NRC, Agreement States, and other organizations
- rationale for change
- accountability
- practicality

The focus group participants recognized that there are options within each option for a National Materials Program and, in some situations, options can be combined. Input from the participants helped the Working Group define the options for a National Materials Program that are outlined in Section III.

## **SECTION III**

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**In Section III, the Working Group discusses six options for a National Materials Program structure. The options were developed through discussions with and comments from stakeholders and reflect the combined expertise of the Working Group members.**

**Section III begins with a brief description of each option followed by a table comparing the six options. Next a written comparison summarizes some key considerations. Following the summary, each option is discussed in depth, starting with the Current Program, which is used as the base case for comparison, and continuing through the range of options.**

## Options for a National Materials Program

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Options for a National Materials Program were examined by the Working Group after considering discussions with and comments from stakeholders. In this report, the following six options were evaluated, beginning with the current program, which is used as a base case.

- 1. Current Program**

Current NRC and Agreement State programs remain in effect. No policy changes are involved. This is the "Base Case" used by the Working Group for comparison of the other options.
- 2. Independent States**

NRC has jurisdiction over federal facilities, areas of exclusive federal jurisdiction, and over certain quantities of special nuclear material. NRC does not provide regulatory oversight of materials programs. "Agreement States" as such do not exist; however, states could regulate materials based on state needs and priorities.
- 3. Minimum NRC Involvement**

NRC may reduce efforts and resources from the current level to a minimal program by making changes to policies concerning implementation of program elements. States continue to become Agreement States and NRC maintains oversight function. Certain elements of a radiation protection program, such as performing inspections, are not directly specified in the AEA, but are necessary to protect public health and safety.
- 4. Alliance**

Current NRC and Agreement State programs continue, but work to develop national regulatory priorities and products in a collaborative manner. Decisions are based on group consensus. Agreement States assume greater responsibility for decisions and for devoting resources to develop regulatory products.
- 5. Delegated Program**

State Agreements as they exist today would cease. NRC develops rules and maintains authority over all licensing and inspection functions. NRC may authorize states to implement the licensing and inspection portion of the program under contract to NRC. Authority is delegated to the state for the term of the contract or agreement.
- 6. Single Regulatory Agency**

Regulatory authority over radioactive materials nationwide is the responsibility of a single federal entity. This entity could be NRC, the Environmental Protection Agency, the Food and Drug Administration, or some new entity responsible for regulating all radioactive material.

## Options for a National Materials Program

*The Working Group considered the current regulatory program structure and a range of other options.*

The Working Group included the current regulatory program in evaluating options for a National Materials Program as a base case. The Working Group also considered extremes to bound its assessment. For example, "Independent States" eliminates NRC oversight and most of its involvement in materials regulation. Conversely, "Single Regulatory Agency" eliminates state authority for radioactive materials regulation.

### Comparison of Options Table

	Current Program (Base Case)	Independent States	Minimum NRC Involvement	Alliance	Delegated Program	Single Regulatory Agency
Change in AEA required	No	Yes (Agreements)	No	Yes (NARM)	Yes (Agreements and NARM)	Yes (Agreements and NARM)
Agreement States	Yes	No	Yes	Yes	No	No
# of Agreement States Assumed	32	0	32	32/50	0	0
NRC jurisdiction over federal facilities	Yes	Yes	Yes	Yes	Yes	Yes
No. of state programs possible	32	50	32	32/50	0	0
No. of states where NRC has jurisdiction	18	0	18	18/0	50	50
NRC licensing	Yes	Yes	Yes	Yes	Yes	Yes
NRC physical inspection	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Guidance development	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Rule development	Yes	Yes	Yes	Yes	Yes	Yes
Evaluation of state regulatory programs	Yes	No	Yes	Yes	Yes	Yes
IMPEP	Yes	No	No	Yes	No	No
Estimated NRC resources in millions and (FTE)	\$55(336)	\$3.7(23)	min. support \$36.7(269) min. program \$32.0(200)	32 states - \$51.6(315)/ 50 states - \$24.7(135)	\$76(368)	\$113(744)

## Comparison of Options

*The Working Group compared and contrasted various attributes of the six options detailed in this report.*

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In contrast to the Current Program, the NRC would probably not support a national radioactive materials program in the **Minimum NRC Involvement Option**. This option considered NRC regulating only AEA material and continuing a voluntary Agreement State program with 32 states. Under this scenario, NRC would retain approximately five thousand licensees, would resemble a very large Agreement State and would maintain only minimum oversight of the Agreement States. In the **Minimum NRC Involvement Option**, NRC would be involved in inspections and guidance development to a limited degree. Because the AEA does not require the review of Agreement States to be as comprehensive as the current IMPEP, NRC would discontinue its use of the IMPEP. The Working Group recognizes the limitations of this option, but it was included to illustrate the impact of policy decisions on resources.

In contrast to the above option, the **Alliance Option** reflects an evolution of the Current Program and offers many enhancements to the current regulatory programs of both NRC and the Agreement States. The **Alliance Option** includes the collaborative development of regulatory products (rules and guidance) to enhance the development of a consistent national program. Agreement States, industry and other stakeholders could participate more fully by jointly setting national priorities and agendas. More resources and people would be shared among all agencies to accomplish the common goals, as defined by the national priorities and agenda, while protecting public health and safety and providing the maximum flexibility when meeting those national goals and priorities. Although IMPEP would be retained in the Alliance, it is possible that it may be changed to reflect new performance indicators required under a National Materials Program.

The three remaining options considered would require changes to the AEA if they were to be implemented. In the **Independent States Option**, a change in the AEA would abolish NRC's materials program for non-federal entities. NRC would not conduct any state oversight. Some states would need to modify their legislation to assume authority over AEA material and may need to adopt a radioactive materials program similar to the program conducted by Agreement States today. Some states may not choose to support a radioactive materials program, and this would create a regulatory gap for AEA materials nationally. The Working Group included this as an extreme to bound the options, though the group determined that it does not meet the mandatory goal of protecting public health and safety. It is possible that states would maintain a voluntary version of the IMPEP. However, without national performance standards, or a mechanism for assuring compliance, the Working Group believes that the IMPEP program would survive only as a set of voluntary guidelines.

## Comparison of Options - cont'd

*The Working Group compared and contrasted various attributes of the six options detailed in this report.*

Another option requiring a change to the AEA would be the **Delegated Program**. This program would abolish the Agreement States program, leaving the entire regulatory program to be run by NRC. This program is envisioned to be similar to the current FDA delegated programs for mammography. Input from stakeholders at the meeting in Arlington, Texas revealed many problems associated with the operation of a delegated program. While many problems can be overcome, the effort to abolish the current program and reconstitute a delegated program across 50 states would be very challenging from cost, organizational and political perspectives. Considerable effort would be expended to change the AEA, abrogate existing agreements, set up a delegated program, negotiate the terms of a delegated program with each state, and to set up a policing function to assure consistency across the delegations. It is possible that a modified form of IMPEP could be retained; however, the Working Group observes that this process would probably be prescriptive and not performance based. In the Working Group's analysis, this option would consume resources at a rate almost equal to that of the Single Regulatory Agency Option.

The third option requiring a change to the AEA is the **Single Regulatory Agency** for AEA material. This would be a reversion to the regulatory program for AEA material of the early 1960's. A change in the AEA would abolish the Agreement State Program and NRC would resume regulation of all byproduct material. A modified IMPEP could be continued on a regional basis; however, the number of regions cannot be estimated. Conceivably, there could be one region for each state (50), or at least a region in larger states and some consolidation of groups of smaller states. When considering this option, the Commission would need to account for reconstituting a large training program to prepare the number of staff necessary to administer such a large centralized program. In general, changes to statutes (of either NRC or Agreement States), costs, time, effort, and effect to the AEA would need to be considered.

Under the **Single Regulatory Agency Option**, NRC resources are projected to increase to absorb work currently conducted under Agreement State programs. This option is inconsistent with the present trend where the federal government is transferring responsibility for all, or parts, of its programs to the states. It also appears to provide the least degree of public confidence as it seeks little input from affected stakeholders and would not accommodate state views.

\* \* \* \* \*

The following portions of this Section describe each option in more detail.

## Current Program

**NRC and 32 Agreement States regulate AEA materials. NRC has leadership responsibility for AEA material and certain oversight functions over Agreement States. The 32 Agreement States and the 18 non-Agreement States have jurisdiction over NARM.**

What are the roles/responsibilities of the NRC for each program element?	NRC is responsible for regulation of AEA materials, licensing, inspection, rule promulgation, guidance development, incident/allegation investigation, and Agreement State oversight. NRC also has regulatory responsibility for federal entities, areas of exclusive federal jurisdiction and materials subject to international safeguards.
What are the roles/responsibilities of Agreement States for each program element?	States have authority for regulation of all radioactive material, licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation.
Are statutory changes required?	No.
What coordination is required?	Coordination exists between the NRC and states individually or through the OAS and CRCPD.
What resources are needed (federal and state)?  Who would pay?	Each regulator provides workforce and financial resources to perform their respective legislative mandates. On joint projects, the NRC pays per diem and travel and states pay salaries and provide time away from routine work.
Accountability	NRC is accountable to Congress, licensees, and public. Agreement States are accountable to State legislative and executive branches of their respective governments, licensees and the public. Agreement States are subject to NRC oversight.
Program Assessment	Agreement States, NRC Regional Offices, and Headquarters sealed source and device (SS&D) evaluation program are periodically reviewed using the IMPEP process.
Program Gaps	NARM is not regulated uniformly, if at all, in non-Agreement States and at federal facilities.

## Current Program

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### Advantages

The Current Program functions in a semi-consultative/advisory way, with NRC assuming a strong leadership role. Section 274 of the AEA emphasized cooperation between NRC and Agreement States. NRC sets standards, determines compatibility for these standards and evaluated adequacy and compatibility of Agreement State programs. The Current Program has established a high nationwide standard for radiation protection for AEA materials. Agreement States apply these standards to non-AEA materials they regulate.

### Disadvantages

No mandate exists in a consultative/advisory relationship for NRC to accept solicited advice, whether it comes from the states, licensees or other stakeholders. The Current Program is not an equal partnership between NRC and Agreement States. Historically, the Current Program has not encouraged NRC to identify and use expertise from states nor has it provided a means for NRC and states to jointly establish a national regulatory agenda.

The Current Program creates duplication of efforts. For example, in Agreement States, licensees that distribute devices to persons who are exempt from licensing must obtain two licenses:

- one from the NRC to distribute devices
- one from the Agreement State to possess radioactive material

Another duplication occurs in writing regulatory guidance. Rules currently are drafted a minimum of three times:

- by NRC
- by CRCPD as a Suggested State Regulation
- by each Agreement State according to its own administrative procedures

## Current Program

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### 1. Roles and Responsibilities of NRC and States for Each Program Element

#### A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

##### States

Agreement States license byproduct, source and special nuclear material in certain quantities, as well as NARM.

Specific licenses are issued. Mechanisms used in specific licensing are reasonably consistent among the states. However, mechanisms for general licenses and the level of communication and contact with general licensees varies widely among Agreement States.

Most Agreement States also have SS&D evaluation programs that include NARM.

The licensed waste disposal facilities in the United States are located in and regulated by the Agreement States of South Carolina, Washington, and Utah.

##### NRC

NRC licenses:

- AEA materials in non-Agreement States
- activities at most federal facilities
- distribution of radioactive devices to persons exempt from licensing
- use and possession of special nuclear material greater than certain quantities
- disposal at sea of byproduct, source and special nuclear materials
- import and export of AEA materials

NRC regions evaluate and issue license for byproduct, source and special nuclear materials. NRC issues specific licenses. NRC uses different mechanisms with General Licensees.

NRC conducts SS&D evaluation program and the exempt distribution program from NRC headquarters office.

NRC does not currently regulate a low-level radioactive waste licensee. NRC does maintain a minimal program that supports 10 CFR Part 61 and provides input to the Commission on policy matters.

## Current Program

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### A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning) - cont'd

#### States

Currently only four Agreement States, Colorado, Texas, Illinois and Washington, have regulatory programs for uranium mining and milling.

Decommissioning licensed facilities in Agreement States is generally an integral part of their licensing and inspection programs.

#### NRC

NRC licenses and inspects uranium recovery facilities in non-Agreement States. NRC also makes final determination on site closures for uranium recovery facilities in all states.

NRC ensures the decommissioning of licensed facilities in accordance with its rules and guidance for formerly licensed sites, the Site Decommissioning Management Plan (SDMP). Decommissioning licensed facilities is performed by NRC licensing and inspection programs. NRC has recently implemented a grant program to Agreement States. Grants will fund evaluation of the remaining formerly licensed AEC/NRC licensees within a state's jurisdiction.

## Current Program

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### B. Performing Materials Inspections

#### States

Agreement States inspect facilities located in their jurisdictions using procedures similar to NRC's IMC 2800. States also conduct inspections of licensees working under reciprocity in their jurisdictions. Reciprocity notifications are required. Each state can establish how long a licensee may operate under reciprocal recognition in their state. The duration for reciprocity ranges from 30 to 365 days in a year.

Agreement States use different mechanisms for providing regulatory oversight for general licensees. The type and frequency of inspection of general licensees varies among the existing regulatory programs.

#### NRC

NRC performs inspections of specific licensees as specified in Inspection Manual Chapter (IMC) 2800. NRC also performs inspections of exempt distribution licensees located in both non-Agreement States and Agreement States.

Reciprocity notifications are required. NRC conducts reciprocity inspections of Agreement States licensees when licensees are working in NRC jurisdictions. NRC may choose to conduct inspections at Agreement States licensee's home office to review activities conducted in areas under NRC jurisdiction. Reciprocity is limited to 180 days in any calendar year.

In FY 2001, NRC implemented rules to register and track certain general licensees using the General License Tracking System.

## **Current Program**

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### **C. Incidents/Allegations**

#### **States**

Agreement State inspection programs investigate incidents and allegations.

As a matter of compatibility, Agreement States are required to report any reportable events to the NRC on a monthly basis. Incidents involving NARM and machine produced radiation may also be reported to NRC to be included in NMED. Incidents involving media attention are also reported.

#### **NRC**

NRC's inspection programs investigate incidents and allegations; NRC tracks allegations separately. The Nuclear Materials Event Database (NMED) is used by the NRC to trend and evaluate events involving equipment and licensees. NRC and Agreement State events are tracked and evaluated by the Generic Assessment Panel to identify safety significant events and generic issues. NRC reports annually to Congress on abnormal occurrences on behalf of NRC and Agreement State licensees. NRC uses some event data to demonstrate accomplishments under its Strategic Plan.

## **Current Program**

### **D. Materials Licensing Guidance, Inspection Guidance and Rulemaking**

#### **States**

Agreement States develop and share guidance with other states. CRCPD coordinates with states through Working Groups that develop some licensing guidance. Some Agreement States develop guidance for their programs independently or by modifying guidance in the NRC's IMC 2800 or NUREG 1556 series. Some states choose to use the NRC's guidance without modification. States also adopt or use guidance in a manner similar to NRC.

Agreement States provide comments to NRC on its rulemaking agenda and on proposed rules. After NRC has established the compatibility level for a rule and adopted it, Agreement States typically have three years from the effective date of that rule in which to adopt the rule or implement other legally binding requirements.

#### **NRC**

NRC develops licensing and inspection guidance for AEA material licenses and requests input from Agreement States. Most licensing guidance is found in the NUREG 1556 series. In developing its guidance, NRC must consider use of existing guidance from standards developing organizations. Guidance from other entities, such as the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), International Atomic Energy Agency (IAEA) or International Standards Organization (ISO), and other professional organizations is also considered when appropriate. NRC responds to documented trends, incidents, inspection findings, petitions, technological advancements and research. NRC establishes the rulemaking agenda, drafts the rule (with Agreement State participation and input for some rules), establishes the compatibility categories for or within each rule, and monitors implementation in keeping with its oversight function.

### **E. Training, Qualifications and Experience Standards for Regulatory Personnel**

#### **States**

Agreement States develop and train staff to meet their program requirements. Many states use training programs developed by NRC. When needed training programs are unavailable, states either contract with groups within their state or join with other states to provide specific training for their staffs. The adequacy of each Agreement State's training program is evaluated during IMPEP reviews.

#### **NRC**

NRC staff are trained and qualified as specified in IMC 1246. The adequacy of training for regional staff is evaluated during IMPEP reviews.

## **Current Program**

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### **2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?**

NRC communicates with others by working with organizations and groups and by distributing information. NRC works with OAS and CRCPD. NRC distributes documents such as All Agreement States Letters, enforcement notices, the Regulatory Agenda, and bulletins to convey information.

Agreement State representation in NRC working groups is often solicited through OAS. NRC and OAS Executive Board review the status and progress of joint Working Groups, receiving information monthly from Working Group chairs. NRC provides no direct funding to the OAS, but funds the transcription services provided for the OAS annual meeting.

NRC has worked with CRCPD for many years. NRC provides funding directly to CRCPD through a federal umbrella grant administered by the Food and Drug Administration (FDA). NRC provides a liaison to the CRCPD's Board of Directors. The liaison participates in all meetings of the Board and serves as a conduit for the flow of information between NRC and CRCPD. CRCPD's working groups modify NRC rules to adapt for state use. CRCPD Working Groups draft rulemaking, guidance and other documents for non-AEA materials which are usually adopted by the states. The CRCPD's SSRCRs are available for use by states.

Individual Agreement State programs coordinate with NRC on routine regulatory issues. States respond to NRC requests for comment on activities such as rulemaking plans, proposed rules, and guidance documents. Agreement States provide personnel to serve on various NRC working groups. Agreement States provide information on incidents, misadministrations, and other activities that assist NRC in evaluating current trends and in fulfilling its responsibility in reporting to Congress. Agreement States must conduct activities such that NRC finds them adequate to protect public health and safety and compatible with the NRC. States, either independently or in groups, may also draft rules as necessary.

### **3. Are Statutory Changes Required for this Option?**

No statutory changes are needed to maintain the current program.

### **4. What Coordination is Required?**

No additional coordination efforts were identified to maintain the current program.

## Current Program

### 5. Resources Needed and Who Pays?

NRC resources support materials licensing, inspection, guidance development, incident/allegations investigations, research, legal advice, adjudication, enforcement, and IMPEP (travel and per diem for state members). Agreement State resources support materials licensing, inspection, guidance development, incident/allegations investigations, legal advice, adjudication, enforcement, and IMPEP (salary for state members). NRC pays travel and per diem for state members on working groups, advisory committee members, and steering committees. States pay the salary for their staff who serve and allow them the time to perform the duties.

NRC resources are also used to support the NMED and SS&D Registry databases with the information being provided by NRC and the Agreement States. NRC and Agreement State resources also support their respective rulemaking processes, including public meetings and the cost of publishing and distributing rules.

CRCPD uses funds provided by NRC to CRCPD through the FDA umbrella grant to develop SSRCRs and technical support documents. NRC resources for various program functions are shown in Figure 3.1. These numbers will be used to compare relative changes to resources for various options described.

**Figure 3.1 - NRC Resources for Current Program**

Activity	Costs* \$ in millions	FTE
NMSS**, Regions	\$ 26.6	197
Direct Support***	\$ 10.0	63
Agency Overhead****	\$ 18.4	76
Total	\$ 55.0	336

\* These resource estimates are based on NRC's FY 2001 budget, and used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.

\*\* NMSS means NRC's Office of Nuclear Materials Safety and Safeguards.

\*\*\* These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

\*\*\*\* These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

## Current Program

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### 6. Accountability

NRC is accountable to Congress for all activities under the AEA. States are accountable to their respective legislative and executive branches of government. State accountability involves activities within state jurisdictions regarding state radiation control statutes and rules. All regulatory agencies are accountable to their licensees and members of the public. Agreement States are required to report certain information to NRC as a matter of compatibility.

### 7. Program Assessment

NRC is responsible for evaluating Agreement State radiation control programs and NRC Regional materials programs. NRC uses an integrated method using common and non-common performance indicators as specified in Management Directive 5.6, Integrated Materials Performance Evaluation Program (IMPEP). NRC's Office of State and Tribal Programs has the leadership responsibility for coordinating Agreement State IMPEP reviews; NRC's Office of Nuclear Materials Safety and Safeguards coordinates NRC regional materials program IMPEP reviews. NRC and Agreement State members are trained to conduct IMPEP reviews. NRC schedules the reviews, assigns the review team members and manages the entire process. Review teams are comprised of three or more members, one of whom is from an Agreement State. A team, comprised of three Agreement State staff and one NRC staff member, was used for the review of Headquarter's SS&D program. The IMPEP review of states evaluates the adequacy and compatibility of the state's programs. NRC uses its IMPEP process to review regional materials programs for adequacy.

### 8. Program Gaps

The AEA does not address NARM. NARM licensees of the NRC located in non-Agreement States and federal facilities are subjected to widely varying regulatory practices. Some non-Agreement States have aggressive licensing or registration programs for these non-AEA materials, while other states have no programs. Federal facilities and Indian tribes located in either Agreement or non-Agreement States can use non-AEA materials without regulatory oversight. For example, an employee of a federal agency (in the performance of official duties) can use a portable device containing NARM without regulatory oversight in any state.

## Independent States

**Independent States assume responsibility for AEA materials in their jurisdictions. Section 274 of the AEA, which includes the Agreement State program, is abolished. No NRC oversight of state programs exists. NRC relinquishes control of AEA materials to the states and maintains authority over federal facilities and certain quantities of special nuclear material. The resulting national program could be either separate independent groups of states that function as one unit but separate from NRC, or fully autonomous states operating independently from one another.**

**This option does not include a mechanism that ensures uniform protection of public health and safety on a national level, but it is included as an extreme to help bound the remaining options.**

What are the roles/responsibilities of NRC for each program element?	NRC is responsible for regulation of AEA materials, licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation only at federal facilities and in areas of exclusive federal jurisdiction. NRC continues to have authority over materials subject to international safeguards. NRC is not responsible for state oversight.
What are the roles/responsibilities of an Agreement State for each program element?	States have authority for regulation of all radioactive material, including licensing, inspection, rule promulgation, guidance development, and incident/allegation investigation functions.
Are statutory changes required?	Changes to the AEA are needed to disassociate NRC from some AEA materials responsibilities. The Agreement State program ceases and states may need to obtain statutory authority to regulate AEA materials.
What coordination is required?	In its purest form, this option would involve no coordination. In practice, states may decide to coordinate through an entity such as OAS or CRCPD.
What resources are needed (federal and state)? Who would pay?	Each entity would fund its own program as necessary to meet its own needs.
Accountability	NRC and states are accountable to the same entities described in the Current Program.
Program assessment	Federal and state regulatory programs would be self-assessing. No federal oversight exists and therefore no assessment of the national program occurs.
Program Gaps	Possible gaps when interstate issues are involved for NARM and AEA materials.

## Independent States

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### Advantages

Independent States option saves some NRC resources because NRC would be relieved of its responsibilities for regulating AEA materials in the states.

States gain complete control over all uses of radioactive materials within their borders, allowing them to develop a homogenous program.

States develop regulatory products and tailor their programs to fit their own needs and have ultimate flexibility.

Regulatory requirements for all radioactive materials are consistent within each state if coordination occurs.

### Disadvantages

NRC retains all of the elements of a materials program because it continues to regulate federal facilities and certain quantities of special nuclear material. However, the scope of NRC's materials program changes because of the different mix of types of licenses and the smaller licensee base. There may be an erosion of expertise within NRC.

Not all states would be willing or able to accept responsibility for regulating AEA materials. Statutory or financial barriers could prevent establishing a more comprehensive program. In addition, a small number of AEA materials licensees in a particular state would also make it impractical to implement a program. As a result, AEA materials may go unregulated in some states.

Lack of compatibility or consistency between state programs could adversely affect licensees who operate in several states to an even greater extent than it currently does. Licensees would be faced with an even greater degree of inconsistency than at present, resulting in higher costs as they deal with these different and possibly divergent programs. Their ability to maintain a compliant operation would be hampered.

Without interstate coordination between individual state regulatory programs, duplication of effort would be unavoidable as each entity took it upon itself to "reinvent the wheel" to respond to radiation safety challenges of changing and new technologies.

## Independent States

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### 1. Roles and Responsibilities of NRC and States for Each Program Element

Under this Option, states have the responsibility for addressing radiation protection program elements. NRC has the responsibility for addressing radiation protection program elements only at federal facilities and in areas of exclusive federal jurisdiction. NRC continues to have authority over materials subject to international safeguards.

### 2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC discontinues its regulatory authority over AEA material in all states, as it does now in Agreement States. In addition, NRC relinquishes its oversight role for adequacy and compatibility of state regulatory programs. However, in several areas NRC may need to retain control:

- a. radioactive material at federal entities, such as VA hospitals and government departments
- b. radioactive material in areas of exclusive federal jurisdiction, such as tribal lands
- c. radioactive material subject to international safeguards such as special nuclear materials in quantities sufficient to form a critical mass and certain other materials, which are the subject of nuclear non-proliferation treaties. Note that the federal government has international treaty obligations related to safeguards of these materials and it is unlikely that these obligations can be transferred to a state.

NRC is responsible for licensing including SS&D evaluations, compliance inspections, investigations, enforcement and development of rulemaking and guidance only to the extent necessary for regulation of materials specified in (a), (b) and (c).

To the extent that each state is willing or able to accept the responsibility, NRC transfers control to each state for all AEA material not covered in (a), (b) and (c) above. Each participating state would be responsible for licensing, compliance inspections, investigations, enforcement, and developing rules and guides. States would also continue to be responsible for low-level waste facilities within their borders.

### 3. Are Statutory Changes Required for this Option?

Changes to the AEA would be required. Revision to relieve NRC of the responsibility for regulating AEA material in all states, and for the oversight of state programs, currently required by Section 274, would be necessary.

For each state to accept this responsibility, state legislation may be needed in order to incorporate AEA materials into their program. Programs may also need to be restructured to accommodate the change.

## Independent States

### 4. What Coordination is Required?

With one or more independent groups of states operating autonomously, a coordinated national effort to harmonize programs would be needed. However, unless all states participated in this coordinated effort, problems of inconsistency and duplication would exist. A redesigned CRCPD could provide the basis for nationwide coordinated effort. On the other hand, if 50 separate states operated their programs autonomously, no coordination would be required.

### 5. Resources Needed and Who Pays?

Each entity would fully fund its own program as necessary, either from license fees, general revenue funds, or combinations of sources. Figure 3.2 compares NRC resources currently expended on various program elements and the resulting change to program costs under this Independent States option.

**Figure 3.2 NRC Resources for Current Program and Independent States Option**

Activity	Current Costs* (\$ in millions)	Current FTE	Independent States Costs (\$ in millions)	Independent States FTE
NMSS, Regions	\$ 26.6	197	\$ 2.0	14
Direct Support**	\$ 10.0	63	\$ 0.4	4
Agency Overhead***	\$ 18.4	76	\$ 1.3	5
Total	\$ 55.0	336	\$ 3.7	23

Source: NRC's FY 2001 budget

\* Costs are the sum of contract support, travel costs and staff salaries and benefits .

\*\* Resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

\*\*\* Resources include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

## Independent States

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NRC continues to be responsible for approximately 500 materials licenses held by federal government departments and in the areas of exclusive federal jurisdiction. This represents approximately 10% of the number of licenses currently under the NRC's control, and because of this, the number of NRC FTE required would decrease. When the reduction would result in less than one FTE, the working group assigned one FTE so that a presence would be maintained. Because NRC's oversight of state programs would no longer be required, and virtually all AEA materials licenses would be turned over to the states, many program elements currently residing at NRC, such as the Office of State and Tribal Programs and NMSS support of state activities would disappear completely. Additional resource decreases are found in the areas of research, licensing, inspection, and writing guidance.

### 6. Accountability

NRC and states are accountable to the same entities described in the Current Program.

### 7. Program Assessment

Section 274 of the AEA would be abolished, along with NRC's oversight authority. NRC would not have oversight responsibility and without a lead federal entity, there would be no formal regulatory program review. However, states might find it beneficial to know the abilities and scope of other state programs. For instance, how out-of-state licenses or SS&D evaluations are accepted from other states would be of interest. In such cases, CRCPD might implement some form of voluntary program review. CRCPD has such a role in Licensing State designations.

### 8. Program Gaps

Significant gaps in radiation protection programs could occur. Seriousness would depend on the degree to which states choose to undertake responsibility for regulating either NARM, AEA material, or both. States may choose to:

- regulate neither AEA material nor NARM
- register NARM
- license NARM
- register (former) AEA material
- license (former) AEA material
- use any combination of the above to regulate the use of radioactive material

In addition to gaps in individual programs, additional gaps due to the lack of formal coordination between state programs could occur. For example, gaps could develop when interstate issues such as reciprocity are involved.

## Minimum NRC Involvement

Minimum NRC Involvement requires NRC to maintain authority over AEA materials. NRC maintains a voluntary Agreement State program. NRC streamlines its operations to continue to meet the minimum requirements of the AEA. NRC can determine the intensity and level of its activity. Depending on how NRC modifies its policies to meet the minimum requirements of an adequate program, cost savings may occur. NRC maintains authority at federal facilities, in non-Agreement States, and over AEA material in Guam, Puerto Rico, U.S. Virgin Islands, and the District of Columbia (unless those entities desired to become an Agreement "State" as provided by Section 274(n)).

Uniform core regulatory requirements would exist in the United States to ensure a consistent approach to regulating the use of AEA material, especially in "basic radiation protection standards and definitions." Promulgation of new rules or modification of existing rules in 10 CFR Parts 19, 30-40, 61, 71, and 150 would either not occur, or occur only when there is a significant need for modification.

Other regulatory activities such as guidance development and research can be modified to allow NRC to meet its minimum legislative requirements. These other activities were not evaluated by the Working Group for their health and safety significance, but could serve as examples for later consideration.

What are the roles/responsibilities of NRC for each program element?	Most program elements common to NRC and states are not specified in the AEA, but exist as policy decisions to execute NRC's charge for maintaining health and safety. NRC modifies its current policies and requires less resources to implement the AEA. <b>The role of NRC in each program element changes due to policy changes.</b> The number of NRC licensees and the number of Agreement States continues to change.
What are the roles/responsibilities of Agreement States for each program element?	Agreement States have responsibility for all elements within their jurisdiction.
Are statutory changes required?	No. This Option assumes the current AEA status, with some NRC policy changes.
What coordination is required?	NRC's OSTP eventually has a larger number of Agreement States to work with, but the basic program structure already exists. Better coordination among Agreement States and with NRC results in better use of resources.
What resources are needed (federal and state)? Who would pay?	Federal resource requirements decrease, but resources continue to be necessary to carry out activities specified in the AEA. NRC needs appropriated funding because of smaller licensee fee base. States continue to fund their own programs.
Accountability	Accountability does not change from the Current Program.
Program assessment	Program assessments can be significantly reduced to match NRC's reduction in resources. IMPEP may be reduced to a telephone call or self-evaluation.
Program Gaps	Program gaps are the same as those identified in the Current Program. Experience and expertise may continue to shift away from NRC with the declining licensee base.

## Minimum NRC Involvement

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### Advantages

NRC and Agreement States would save resources. NRC probably would decrease rulemaking which decreases corresponding state efforts.

### Disadvantages

NRC must develop less resource-intensive methods to assure that public health and safety is maintained.

If NRC reduced or eliminated IMPEP and NMED, there might not be a centralized source of information for NRC to assess the efficacy of the national program.

Some licensees will continue to be subject to more than one regulatory agency, and licensees with interstate activities will continue to deal with multiple jurisdictions and rules.

Minimum NRC involvement reduces coordination between NRC and States.

## Minimum NRC Involvement

### 1. Roles and Responsibilities of NRC and States for Each Program Element

#### A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

##### States

Minimal changes would be required in Agreement State programs. If NRC issues more types of general licenses, states would be requested by industry to do the same. If exempt distribution could be authorized by Agreement States, minimal effects to Agreement States and savings for licensees could result.

Agreement States that perform safety evaluations would continue to do so. States that have agreed to let NRC do such evaluations may need to develop an evaluation program.

States would be responsible for addressing all new issues developing in the waste arena.

There would be no change to uranium recovery or decommissioning programs.

##### NRC

NRC could modify how it licenses AEA material. For example, the number and frequency of licenses reviewed and issued could be decreased by expanding general licensing and/or establishing a registration program.

The *a priori* safety evaluation of SS&Ds containing AEA material is not specified in the AEA, therefore, NRC could evaluate each device every time a licensee wishes authorization to use such a device. However, this is not an efficient mechanism for licensing. NRC continuing to issue SS&D evaluations would be the best alternative. On the other hand, the requirement for NRC to maintain a SS&D registry is not specified in the AEA. This task could be eliminated, contracted, or published on a website, with each regulatory agency voluntarily posting information.

The Low-Level Radioactive Waste Policy Amendments Act of 1985 gave states responsibility to dispose of low-level waste generated within their borders. It allows states to form Compacts to locate facilities to serve a group of States. Staff in the reactor arena could assist with some low-level waste issues.

There would be no change to the current uranium recovery and decommissioning programs.

## Minimum NRC Involvement

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### B. Performing Materials Inspections

#### States

There would be no change required in the Agreement State programs.

#### NRC

Inspection of licensees is not specified in the AEA; however, the Working Group has identified an inspection program to be a necessary component of an adequate program. The scope of NRC's inspection program is policy driven; therefore, NRC could modify its method of performing inspections by contracting inspections, or by allowing self-inspections by licensees, with NRC retaining the final determination of public health and safety. In addition, NRC could modify the scope and frequency of inspection of licensees, including reciprocity inspections in the non-Agreement States, territories, and the District of Columbia.

### C. Incidents/Allegations

#### States

No change would be required in the Agreement State incident response programs. Agreement States would no longer be required to report to NRC if NMED is eliminated, or would be required to report only the most egregious incidents to a scaled-back NMED.

#### NRC

NRC response would be limited to licensees under NRC jurisdiction. The NMED system, used for generic assessment and event tracking, is not required under the AEA, and could be limited to NRC-licensee events. Under the most far reaching changes to NRC's program, NMED could be deleted.

## **Minimum NRC Involvement**

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### **D. Materials Licensing Guidance, Inspection Guidance and Rulemaking**

#### **States**

As NRC generates fewer changes to rules, state rulemaking will decrease and fewer compatibility issues will result. Agreement States would continue to develop individualized rules, but would continue to be required to be compatible with NRC's basic radiation protection standards.

Agreement States would use sources of information from CRCPD's SSRCRs, standard developing organizations, and other federal and state agencies.

#### **NRC**

NRC would need rulemaking resources for basic radiation protection standards and amending 10 CFR Parts 19, 30 through 40, 61,71 and 150. NRC would rely heavily on other entities for developing standards and rules; NRC would follow the Administrative Procedures Act for final adoption of rules.

NRC's activity in developing or maintaining guidance documents could range from non-existent to limited, for instance, to developing some basic documents related to radiation safety.

### **E. Training, Qualifications and Experience Standards for Regulatory Personnel**

#### **States**

Each state is responsible for maintaining a level of staffing that is adequate to provide public health and safety. Therefore, each state must make sure that staff have adequate training. This option would affect those states that use NRC's current training program because NRC would reduce training opportunities.

#### **NRC**

Depending on the assumptions made, NRC's staffing could change dramatically. Increasing the use of general licensing and performing fewer inspections would decrease the number of staff requiring training and qualifying in accordance with NRC's IMC 1246. NRC's Technical Training program would be significantly decreased for the materials arena.

## Minimum NRC Involvement

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### 2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

NRC responsibilities continue under the current AEA in:

- standard setting
- oversight of Agreement State programs for adequacy and compatibility
- regulation of licensees in non-Agreement States
- regulation of Federal agencies, areas of exclusive federal jurisdiction, tribal lands
- production and utilization facilities, special nuclear materials (above certain amount)
- disposal in the ocean
- high level waste disposal
- off-shore waters
- certain aspects of mill tailings

This option would require NRC to make dramatic policy changes for executing its obligations. For instance, the AEA requires that NRC take the leadership role in regulation of AEA material throughout the U.S., but it does not define the level of effort required of NRC to meet that statutory obligation. NRC's focus on regulatory research would be in support of the basic radiation safety standards contained in 10 CFR Part 20. Therefore, NRC resource requirements for materials programs would decrease significantly because basic radiation safety would be addressed in the reactor safety arena, with assistance from the materials arena when needed.

This Option requires the NRC to fulfill its obligations under the AEA, but would also include program elements identified by the Working Group as being necessary for an adequate radiation protection program. The Working Group considered more radical changes that were determined not to be protective of public health and safety. For this reason, these were not pursued further.

### 3. Are Statutory Changes Required for this Option?

This Option assumes no changes to statutory requirements are necessary for NRC, or for the states.

Without change to the AEA, NRC would establish a minimum level of resources necessary to perform its duties, regardless of the number of licensees or the number of Agreement States. With changes in certain policy decisions, NRC could minimize its current level of effort. This could include elimination of NMED and IMPEP.

## **Minimum NRC Involvement**

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### **4. What Coordination is Required?**

With the potential minimization of the NRC's program, more collaborative interactions among the states would be required. NRC may continue to need to gather information from all states for unusual events and abnormal occurrences, depending upon policy changes made. Coordinated training would be necessary because the expertise will be shifting from NRC to the states for many categories of licensees.

### **5. Resources Needed and Who Pays?**

The overall effect is minimal for states, but could result in savings for the NRC because fewer NRC resources would be required to support this program. As indicated earlier in this document, the Working Group used the current program as the base case. Compared to the current program, NRC could reduce its resource needs by changing regulatory policy, thus varying the scope of activities, rather than changing statutes. A "minimum" NRC presence could include a wide range of options, depending on the degree to which NRC policy might change.

Because it is impossible to predict what level of regulatory oversight NRC would adopt by policy under a given minimum program, the Working Group evaluated a range of options. Two variations are presented in Figure 3.3 below.

## Minimum NRC Involvement

**Figure 3.3 - NRC Resources for Current Program and Minimum NRC Involvement**

<b>Activity</b>	<b>Current Program Costs*</b> (\$ in millions) (FTE)	<b>Minimum Support Option+</b> (\$ in millions) (FTE)	<b>Minimum NRC Program Option++</b> (\$ in millions) (FTE)
NMSS, Regions	\$ 26.6 (197)	\$ 16.7 (158)	\$ 15.0 (105)
Direct Support**	\$ 10.0 (63)	\$ 5.3 (50)	\$ 6.0 (50)
Agency Overhead***	\$ 18.4 (76)	\$ 14.7 (61)	\$ 11.0 (45)
<b>Total</b>	<b>\$ 55.0 (336)</b>	<b>\$ 36.7 (269)</b>	<b>\$ 32.0 (200)</b>

- \* These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.
- \*\* These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.
- \*\*\* These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).
- + This option assumes the NRC licensing and inspection programs do not change, but rule and guidance development are reduced substantially, the general license program is assumed to support follow up for a second round of registrations, NMED and event evaluation support only NRC's licensees, the orphan source and low level radioactive waste programs are eliminated and state program activities are limited to interactions with perspective Agreement States, review of Agreement States and reduced interactions with OAS and CRCPD.
- ++ This option assumes no materials research, guidance development, IMPEP, orphan source program, or grants for terminated sites in Agreement States; no NMED and no onsite inspections other than in response to incidents. In addition, rulemaking and support to Agreement States are reduced.

### 6. Accountability

NRC and states are accountable to the same entities described in the Current Program.

## **Minimum NRC Involvement**

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### **7. Program Assessment**

The AEA requires NRC to evaluate the adequacy and compatibility of Agreement State programs but the AEA does not specify the depth or scope of reviews. This program effort could be minimized through the modification or elimination of the current Agreement State oversight program, including IMPEP. For example, during the initial years of the Agreement State program, evaluations consisted of only a short visit from a regional NRC representative. Agreement State reviews could be reduced to a visit from an NRC representative, a telephone call update, or the state could be requested to complete a questionnaire for NRC to review and maintain on file.

This Option would require no change to existing agreements between NRC and the States.

### **8. Program Gaps**

Similar to the current structure, non-AEA material at facilities, territories, and states not entering into Agreements is not addressed by this option.

## Alliance

An Alliance is a cooperative process between the States and NRC that identifies radiation safety regulatory priorities and the means to address those priorities. The process may operate between the States and NRC or it may involve other federal and state regulatory agencies on radiation issues.

The Alliance Option is the structure that most completely encompasses the common attributes of shared goals and decision-making, shared resources, and shared responsibility.

The Alliance requires a consensus structure, one based on general agreement and consists of decisions/judgements arrived at by most of those concerned. Consensus does not indicate unanimity of a group, but is a process that provides an opportunity for all parties in the group to bring their individual ideas, opinions, and input to the table so that participants are empowered and can agree to accept decisions made by the group.

What are the roles/responsibilities of the NRC for each program element?	NRC and states share responsibility for - identification of regulatory products - prioritization of product development - development of corresponding rules and guidance. NRC would obtain authority for discrete NARM.
What are the roles/responsibilities of Agreement States for each program element?	NRC and states share responsibility for - identification of regulatory products - prioritization of product development - development of corresponding rules and guidance.
Are statutory changes required?	Yes, to eliminate the regulatory gap for NARM.
What coordination is required?	More efficient coordination between the NRC, states, OAS and CRCPD is required.
What resources are needed (federal and state)? Who would pay?	Each regulator provides the workforce and financial resources to carry out their respective legislative mandates. On joint projects, NRC pays for per diem and travel and states pay salaries and provide time to work on Alliance activities. NRC also covers most of infrastructure, e.g., publications, national databases, etc.
Accountability	No change from the Current Program.
Program assessment	Program assessment through IMPEP, including review of states, Regions and NRC Headquarters for SS&D review.
Program Gaps	AEA would need to be amended to include NARM. The only gap regarding radioactive materials would be diffuse NORM.

**NOTE CONCERNING RESOURCES:** For states, out-of-state travel is more than just a budgetary issue. Often because of policy/political issues, unless funded by someone other than the state, state employees are not allowed to travel out-of-state.

## Alliance

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### Advantages

The Alliance option most completely encompasses the common attributes desired in a National Materials Program. Attributes consist of shared goals and decision-making, shared resources, and shared responsibility.

Advantages to a consensus structure are that all parties have an opportunity, if not an obligation, to participate meaningfully in a spirit of true partnership.

Benefits of consistency in the program result, demands on resources are spread among the participants, and sharing of responsibility occurs. These accomplishments inspire public confidence.

Obvious resource savings accrue when resources are shared.

### Disadvantages

Negotiations to achieve consensus require time and resources. Sometimes these costs could be significant. Individuals who participate would need the authority to make the decisions necessary to reach consensus. This may not always be the case.

This option assumes NRC would obtain authority to regulate discrete NARM. This could result in some non-Agreement State radioactive materials programs being dissolved, unless the option encouraged or forced non-Agreement States to seek Agreement State status.

## Alliance

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### 1. Roles and Responsibilities of NRC and States for Each Program Element

#### A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

These activities would be performed as they are in the Current Program. Contracted entities or Centers of Expertise could be used to perform some license reviews or portions of reviews for specific technical areas.

#### B. Performing Materials Inspections

The current inspection program would be maintained, but would be supplemented with other options. NRC would perform inspections for all facilities authorized to possess and use radioactive materials (now including NARM) in non-Agreement States and at federal facilities in Agreement States. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-Agreement States and Agreement States.

Other options include:

1. allowing other entities to contract with NRC and Agreement States to perform inspections and report results to the appropriate regulatory agency;
2. allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC and Agreement States or reduce inspection effort by NRC and Agreement States\*;
3. accept audits performed by other organizations and use these as a supplement to NRC and Agreement State inspections to reduce inspection effort by NRC and Agreement States\*; or
4. use Centers of Excellence to perform inspections of specific technical areas.

\*Acceptance of licensee audits or audits performed by independent organizations to modify NRC and Agreement State inspection effort would be determined by the appropriate regulatory agency in a selective manner. Centers of Expertise could be either Agreement State or NRC organizations and would be jointly recognized by NRC and Agreement States.

#### C. Incidents/Allegations

A national Information Infrastructure regarding incidents will need to be maintained.

## Alliance

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### **D. Materials Licensing Guidance, Inspection Guidance and Rulemaking**

Development of rules and guidance is discussed in detail in "Regulatory Process Under the Alliance" later in this section.

### **E. Training, Qualifications and Experience Standards for Regulatory Personnel**

The current training, qualifications, and experience standards would be maintained and be enhanced with:

1. use of an Information Infrastructure for training ideas, resources, and opportunities designed for or employed by NRC and Agreement States
2. allowing licensees to provide training, on a voluntary basis, for specific technical issues or consider contracting with licensees to train staff in specific technical areas
3. encouraging a regulatory agency exchange program to develop staff in specific technical areas

### **2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?**

NRC and States share responsibilities except where noted. NRC maintains oversight for adequacy. NRC funds and continues to coordinate and participate in the IMPEP process. Equal participation under the IMPEP process, with voting status on the management review board for States, should be considered.

The roles and responsibilities of the CRCPD and OAS can vary under the Alliance, depending upon decisions made by the Commission regarding a National Materials Program.

### **3. Are Statutory Changes Required for this Option?**

Congress would need to make statutory changes to authorize NRC authority for NARM. A few Agreement States may have to amend laws so that they may adopt Alliance products. Some laws currently require states to adopt SSRCRs developed by CRCPD.

## Alliance

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### 4. What Coordination is Required?

Activities of CRCPD that could be impacted by the Alliance are development of the SSRCRs and the products developed by many of the Environmental Council Committees. In anticipation of potential changes, the CRCPD Board created a committee to evaluate the CRCPD's role in radioactive materials rulemaking and make recommendations to the Board concerning changes in that role. This committee is coordinating its efforts with the National Materials Program Working Group.

OAS activities involving assignment of persons to NRC working groups could be similarly impacted. OAS issues could potentially be addressed through the Alliance process.

Both organizations are involved with the Working Group and are aware of the potential need to evaluate and change the functions of the organizations. Any changes made will be dependent upon the Commission's decision regarding a National Materials Program. If that decision incorporates the Alliance, changes in the organizations will be geared toward reducing duplicate efforts and increasing efficient use of resources.

### 5. Resources Needed and Who Pays?

Sharing responsibilities with the states would reduce costs to the NRC. While NRC would be required to issue rules, developing them in collaboration with the states will reduce NRC costs. For areas not involving the "core" concerns of the NRC, NRC may not need to be involved in a rulemaking at all, or be involved at a minimum level of effort. The NRC could then choose to adopt the rule through its normal rulemaking process.

Priorities set by decision-makers for the NRC and states are set by those who can commit resources. Resources committed by the states are expected to be the same type of resources currently committed. For example, when a state representative participates on a working group or an IMPEP team, the state pays the position costs and NRC pays the travel and per diem. Because many states have difficulty funding out-of-state travel, it is preferable that NRC continue to cover travel and per diem. With proper planning and use of conference calls, the majority of the expense for developing a regulation or guidance document would fall to the states that had the leadership role.

Both licensees and taxpayers would pay for the cost of a National Materials Program. The mix between the two will depend on the legislature controlling each agency's budget. It is not expected that all agencies will be equally involved in all areas. On priorities that are high, several agencies will participate, thus spreading the cost. An agency may work on a product independently, either because it chooses to, it is required to by legislation, or as a result of a petition that is not related to a national priority. In that case, the agency, and its licensees and its taxpayers, will cover the entire cost of the work.

## Alliance

NRC will regulate NARM. This should not result in a significant increase in resources for the NRC in most categories of licenses. The vast majority of non-Agreement State NORM licensees are already licensed by the NRC because of the AEA materials they use. Regulatory burden for those licensees that are now licensed by both NRC and the non-Agreement States would be reduced. NRC currently devotes resources to NARM. For instance, NRC investigated Mallinckrodt overexposures from NARM. NRC has been involved in issues concerning pre-1978 mill tailings.

Budgeting would be similar to the Current Program. Each regulatory agency would continue to be responsible for the budget necessary to carry out its licensing and inspection activities.

Likewise, each agency would be responsible for directions imposed on it by its legislature and for responding to petitions for rulemaking. Activities conducted jointly among agencies through the Alliance as national priorities are those that the other agencies would have supported independently.

Funding for the Alliance Administrative Core should be evaluated by an implementation committee after CRCPD, NRC, and OAS agree to a formal working relationship with formal communication channels. The functions of the Administrative Core (discussed in detail later in this section) are currently being performed and funded, sometimes in duplication, among states, NRC, CRCPD, and OAS. Some roles will be increased and some will decrease. Efficiencies should reduce overall costs.

The following chart shows current costs and the cost of an Alliance option depending upon the number of Agreement States.

**Figure 3.4 - NRC Resources for Current Program and Alliance Option**

Activity	Current Program Costs* (\$ in millions) (FTE)	Alliance (32 States)* (\$ in millions) (FTE)	Alliance (50 States)** (\$ in millions) (FTE)
NMSS, Regions	\$ 26.6 (197)	\$ 24.3 (181)	\$ 9.4 (58)
Direct Support	\$ 10.0 (63)	\$ 10.0 (63)	\$ 7.9 (46)
Agency Overhead	\$ 18.4 (76)	\$ 17.3 (71)	\$ 7.4 (31)
Total	\$ 55.0 (336)	\$ 51.6 (315)	\$ 24.7 (135)

\* These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.

\*\* These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

\*\*\* These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

## **Alliance**

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The Alliance requires a greater commitment of resources compared to other options, but the benefits are significant. Measurement of public confidence is difficult, but the Working Group believes this Option promotes harmony among regulators, encourages public participation, utilizes Centers of Expertise, and makes setting national priorities a very open and participatory process. These things build a stronger national program, which can then enhance public perception of efforts to protect workers and public health and safety.

### **6. Accountability**

NRC and states are accountable to the same entities described in the Current Program.

### **7. Program Assessment**

NRC would retain its responsibility to evaluate Agreement State radiation control programs and NRC regional materials programs using IMPEP. Under an Alliance, NRC may consider allowing an Agreement State representative to be a voting member of the Management Review Board.

### **8. Program Gaps**

If the AEA is amended to incorporate discrete NARM, as recommended by the Working Group and stakeholders, the Working Group does not envision any program gaps other than the regulation of diffuse NORM.

## Alliance Makeup and Structure

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The Alliance consists of three groups: regulatory decision-makers, other stakeholders, and an administrative core.

*Regulatory decision-makers* are state radiation regulatory program managers and NRC materials program managers. Regulation of sources of radiation is a regulatory function. By statute, federal and state agencies are charged with this regulatory responsibility. Therefore, these agencies are the ultimate decision-makers regarding radiation regulation, are essential to the regulatory process, and are the central component of the Alliance.

It is also hoped that under the Alliance, regulatory decision-makers would include, or seek the input of other federal and state agencies charged with regulating radiation issues. Other agencies could include EPA, DOE, and equivalent state environmental or health agencies depending on where the state radiation control program is organizationally located.

*Other stakeholders* include licensees, the public, professional organizations, industry organizations, and other federal and state agencies with an interest in radiation issues. The other federal and state agencies are considered stakeholders because at this time, the effort towards establishing a National Materials Program is being driven by NRC and representatives from the state radiation regulatory agencies. Regulatory decisions by federal and state agencies must be informed decisions. To make such decisions, it is necessary to actively seek and consider input from those persons who would be effected. Stakeholders are also essential to the regulatory process and should be considered as such by the Alliance, as they currently are by individual federal and state agencies.

The *administrative core* can be considered the support staff for the Alliance membership and is essential to the logistical process of the Alliance.

### The Role of the Regulatory Decision-Makers

The responsibilities of the regulatory decision-makers within the Alliance include:

1. jointly establishing regulatory priorities and agenda
2. identifying Centers of Expertise
3. recognizing current regulatory successes
4. identifying alternate resources
5. defining/making assignments and committing resources
6. evaluating progress on assignments
7. maintaining a "group" to serve as a coordination interface on Alliance issues

## **Alliance Makeup and Structure**

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### 1. Jointly establishing regulatory priorities and agenda

The Alliance structure supports consensus and provides an opportunity for all parties to bring their individual ideas, opinions, and input to the table. This creates an open forum for regulatory decision-makers to discuss issues. Presumably, the regulatory decision-makers are aware of federal or state agency radiation control priorities and resources. In an open forum created by the Alliance, all the decision-makers may become aware of pertinent regulatory issues across the nation concerning ionizing radiation (both AEA designated radioactive materials and NARM). As has been the case, issues involving NARM can be of higher priority to the state programs that have authority to regulate those materials than other issues involving AEA-designated materials. By bringing all issues to the table, regulatory priorities, an agenda for resolving them, and suggested regulatory products can truly represent national priorities rather than priorities limited to those radioactive materials that NRC has the authority to regulate. (Regulatory products suggested may include rules, licensing, inspection, and technical guidance documents, etc.)

Jointly establishing priorities and an agenda does not prohibit regulatory agencies from addressing other issues that are identified. For example, during the 2000 OAS meeting, a group of states representatives volunteered to work together and have developed guidance on positron emission tomography (PET), although it was not identified as one of the top three priorities during the tabletop exercise.

### 2. Identifying Centers of Expertise

Using Centers of Expertise to develop regulatory products was identified as an efficient and preferred method during the evaluation of the essential program elements of a National Materials Program. The most up-to-date knowledge and experience involving any one given use of radioactive material does not lie within any one federal or state agency. Since the inception of the Agreement State concept, Agreement State regulatory programs have not only increased in number, but have matured in knowledge and experience with the various uses of radioactive materials. In numerous situations, Agreement States have the most current knowledge and experience because the uses of radioactive material are often concentrated in certain parts of the country. For instance, well-logging and industrial radiography are more unique to the oil-producing states. Regulation of certain radioactive material is located only in Agreement States, as with licensing and inspection of existing waste disposal sites. Agreement States and Non-Agreement States have knowledge, experience, and statutory authority and responsibility that NRC does not have. Therefore, the Centers of Expertise primarily reside at the state level in those situations. The regulatory decision-makers will identify those Centers of Expertise on a nationwide basis for a particular radiation regulatory issue.

## Alliance Makeup and Structure

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### 3. Recognizing current regulatory successes

It is rarely of benefit to “reinvent the wheel” that is turning effectively and efficiently. In evaluating the program elements, the Working Group determined that the current method of accomplishing several of the elements was the most effective or was one of several effective options. Individual agencies, federal or state, have developed alternative methods for accomplishing program elements. The Alliance allows identification and recognition of current successes, and ultimately, more efficiently-produced regulatory products.

### 4. Identifying alternate resources

The Alliance provides an opportunity to create a collection point for alternate resources that can be used by regulatory agencies. It is not necessary for each federal and state regulatory agency to produce a regulatory product from scratch. It is inefficient to operate under the presumption that a regulatory product can only be valid and recognized by regulatory agencies if that product is initiated, reviewed, and produced by a particular regulatory agency. Federal agencies are required to use consensus standards, unless other options are justified. State agencies frequently share regulatory products. Both federal and state regulatory products often reference other rules and guidance documents, and industry standards. This collection of alternate resources should include not only regulatory products and consensus standards, but also professional and industry organizations that can be used in the developing regulatory products.

### 5. Defining/making assignments and committing resources

Under the Alliance, groups of regulatory staff members would be assigned to develop a regulatory product for a particular issue. Membership on those work groups would be made considering the Centers of Expertise for that particular issue, the availability of staff to participate on the work group and a regulatory agency’s statutory jurisdiction to regulate that particular issue. Creating these work groups focuses the pertinent national resources for particular issues. The Alliance establishes work groups and makes assignments. The work groups are also made cognizant of and should use, where appropriate, the current successes and alternate resources identified by the Alliance.

Because assignment of federal and/or state personnel to a work group involves a commitment of resources, those individuals making the assignment must be empowered to commit those resources. For this and other reasons, the primary membership of the Alliance consists of the regulatory decision-makers. Whether the committed resources involve money, staff member time, or both, assignment of such resources is a commitment towards a mutually established national radiation control priority.

## Alliance Makeup and Structure

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### 6. Evaluating progress on assignments

Progress on those priorities must be evaluated to ensure that the mutually agreed upon national radiation control priorities are addressed in a timely and appropriate manner. The regulatory decision-makers in the Alliance have committed the appropriate resources and should evaluate whether the progress is satisfactory or not. For instance, if time lines were established and not met, the regulatory decision-makers would evaluate the reasons why and make appropriate adjustments to ensure the product is developed and the national radiation control priority is met.

### 7. Maintaining a "group" to serve as a coordination interface on Alliance issues

Regulatory decision-makers constitute a large group which will require a coordination interface for communicating within the Alliance. The "interface group" will act as a spokesperson for Alliance issues. The regulatory decision-makers as a whole will designate the membership "group," which should include representatives from both states and NRC.

### **Role of the Administrative Core**

The Alliance requires an administrative component of the regulatory core. The administrative component could consist of a few representatives of states and NRC, or could be a separate entity, as employed by the CRCPD or the Health Physics Society. No decisions or actions on technical or policy issues or established priorities may be made by the administrative component of the Alliance; this would negate the consensus nature of the Alliance.

The responsibilities of the administrative core within the Alliance include:

#### 1. Planning, coordination and logistics

A support staff function is necessary for Alliance members. The support staff functions must include coordinating the logistics of Alliance meetings, whether those meetings are physical or virtual meetings. Meeting locales and reservations must be arranged and notification of the arrangements must be made to the Alliance members. An agenda for the meeting must be created and distributed. The support group could provide facilitation for these meetings.

Because the primary membership of the Alliance represents multiple organizations, no one organization should represent the Alliance. However, the membership of the Alliance, including stakeholders, need a centralized point of contact for logistical purposes.

## **Alliance Makeup and Structure**

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### **2. Tracking Alliance assignments/products**

Regulatory decision-makers are tasked with identifying priorities and making assignments. Support staff must maintain documentation of those priorities and assignments, including the desired products, the individuals assigned, and any time lines associated with the assignments. The administrative core will need access to this information and be able to report to the regulatory decision-makers who are responsible for evaluating progress.

### **3. Maintaining Information Infrastructure**

The roles of the regulatory decision-makers include identifying Centers of Expertise and alternative resources and recognizing current successes. The work groups assigned the development of regulatory products should utilize these Centers of Expertise, alternative resources, and current successes. An Information Infrastructure provides a centralized point for collection of this information and any such data collection needs maintenance. Maintenance of the Information Infrastructure is a support staff function and therefore, a role of the administrative core of the Alliance.

### **Role of the Stakeholders**

Federal and state agencies must make informed regulatory decisions, and under the Alliance would still be required to actively seek and consider input from those persons who would be affected. Stakeholder input would be directed to the Alliance for the regulatory products being developed. For example, if the Alliance work product were a rule, comments on the rule would be directed to the work group assigned to the rule. Any comments directed to NRC or an individual state agency should be forwarded to the work group.

The Alliance in no way negates the opportunity for stakeholders to seek information and provide input to the NRC or to any individual state agency. Developing regulatory products under the Alliance allows stakeholders input and access to a larger audience of decision-makers.

### **Alliance Characteristics and Functions**

Although the Alliance is not a structure in itself, it must operate within a framework. It must have operating procedures in order to function. The framework can vary depending upon the commitment or resources by those involved.

## Alliance Makeup and Structure

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The Alliance can conduct physical or virtual meetings with the decision-makers from all states and the appropriate managers from NRC. The meetings could be held at an established frequency, such as annually. This provides an opportunity for true consensus because everyone comes to the table and has opportunity for input. Not all states are expected to fully participate, as is the case now. Some states may be more active than others.

Instead of having each individual decision-maker present, representatives of the states and NRC could meet. Decision-makers not present would need to agree to having a representative present their input. It would also require the representative to make greater preparation prior to the meeting by soliciting the opinions and feedback from those decision-makers being represented. From an operational standpoint, the Alliance would need to determine a method of designating the representatives. However, representatives will not be able to commit resources on behalf of all Alliance members. Furthermore, caution would need to be exercised to ensure the consensus of the Alliance was represented.

Work groups assigned regulatory products by the regulatory decision-makers could consist of varying combinations of state and NRC staff, depending on the issue and product being developed. The work groups could consist solely of members from interested states, especially for an issue or product over which NRC has no statutory jurisdiction (non-AEA sources of radiation). Or the work group could consist solely of NRC staff for an issue or product over which state staff have no jurisdiction (federal facilities). The work groups could consist solely of Centers of Expertise for a particular technical issue or could have Centers of Expertise and additional resource members.

The administrative core of the Alliance is a support staff function and can operate in varying ways. It can exist within NRC, in which case, those administrative core members would be federal employees, specifically NRC employees. They could be located within Office of State and Tribal Programs because of that program's existing relationship with the Agreement State programs. However, the non-Agreement States are ideally also a part of the Alliance and would need to be considered. The administrative core functions could be managed by a non-regulatory entity and be funded through contractual funds, such as the current relationship between the Health Physics Society and Burke and Associates. The administrative core

functions could also be managed through an existing organizational entity such as NRC or CRCPD's Office of Executive Director, with the addition of FTE(s) and monetary support. The NRC & CRCPD already perform these functions in support of a national regulatory program. Regardless of how the administrative core is staffed and where it is located, compatible information technology capabilities will be required in order to fulfill the responsibilities of maintaining the Information Infrastructure and being the central coordination/contact point for the Alliance.

## Alliance Makeup and Structure

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### Regulatory Process under the Alliance

Work for the Alliance will be done on a voluntary basis. While each agency must develop rules and guidance based on its own needs, legislation and political necessities, the Alliance will allow agencies with similar needs to work together cooperatively. When they work together, resources of staff, money and time are saved.

Under the Alliance, certain fundamental principals will apply for the development of rules and guidance.

1. Rules and guidance will be developed in partnership using Centers of Expertise.  
A standing committee made up of Alliance members - both state and NRC will determine compatibility.
2. Not all Centers of Expertise may want to participate.
3. Each agency must still meet its administrative procedures for the adoption of rules.
4. The Commission will maintain its role in ensuring the framework for a National Materials Program through its ultimate adoption of criteria for adequacy and compatibility for rules

The process will be as follows:

1. Alliance meets and establishes priorities.
2. Regulatory change is identified.<sup>1</sup>
3. Define the work product – e.g., regulation or guidance, scope and depth.
4. Identify Centers of Expertise and establish a working group.
5. Set schedule.
5. The working group drafts the rule, statement of consideration and regulatory analysis, and proposes the level of compatibility.
7. The Alliance's Standing Compatibility Committee assigns compatibility category.
8. Peer review – Alliance and interested stakeholders.
9. Working group reviews comments. If major changes to rule are needed, or, if based on comments, the Working Group believes the proposed compatibility should be changed, the process goes back to step 6.

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<sup>1</sup> A change may be identified as a national priority, or some states may agree to cooperate on one of their priorities that did not elevate to a national priority.

## Alliance Makeup and Structure

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10. If there are no major changes to the rule and no changes to compatibility, the draft is distributed to Alliance members, Agreements States and NRC, with a description of changes since the draft was reviewed.
11. Each agency adopts the rule dependent on desire, internal needs, and compatibility, pursuant to its own administrative procedures.<sup>2</sup>

The role of the Alliance will be to:

1. identify priorities (these may be national priorities, or the alliance may facilitate several agencies working together on priorities that are not elevated to a "national priority")
2. define work product, e.g. rule, guidance or procedure
3. establish the scope, depth and time frame for the product development
4. identify resources needed, e.g. stakeholders, "associates"

The Working Group established to develop the rule Suggested Regulation or guidance will:

1. select a chair(s)
2. develop product
3. report progress
4. have the product peer reviewed and evaluate comments
5. submit the product to the Alliance core

The Alliance's Administrative Core will track and report on the working group's progress, and when finalized, distribute the product to the Alliance members and the Alliance's Information Infrastructure.

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<sup>2</sup> The Working Group proposes that the current 3-year implementation criteria will be continued under the Alliance.

## Delegated Program

**NRC or some other federal entity establishes requirements for licensing and inspection of all radioactive material. States would no longer hold Agreements with NRC, but NRC would be able to delegate certain duties to states. Note that this Option allows for delegation of duties, not authority.**

What are the roles/responsibilities of the NRC for each program element?	NRC is responsible for developing a National Materials Program to meet all program elements.
What is the role/responsibility of an Agreement State for each program element?	Agreement States would cease to exist. States could contract with NRC to perform some duties from program elements.
Are statutory changes required?	The AEA must be amended to include NARM, delete the Agreement State program, and add provisions to include delegated programs. States may also need to modify their legislation.
What coordination is required?	NRC must coordinate efforts on a national level to ensure no program gaps are created.
What resources are needed (federal and state)? Who would pay?	Licensees would pay, and NRC would provide funding to states according to the terms of each contract.
Accountability	NRC would be accountable to the licensees and the public. States would be accountable to NRC under the terms of their contracts.
Program Assessment	NRC would assess the performance of each state performing delegated duties at the time of contract renewal at a minimum.
Program Gaps	This Option assumes the AEA is amended to include NARM. NRC essentially has responsibility for regulating all radioactive material in the US under this Option, therefore eliminating program gaps.

## Delegated Program

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### **Examples of Two Existing Delegated Programs**

*The Environmental Protection Agency (EPA) currently delegates some of its programs to states. The Food and Drug Administration (FDA) also delegates programs under the Mammography Quality Standards Act (MQSA). The Working Group chose to model the Delegated Program option after the FDA's MQSA program because:*

- 1. many of EPA's delegated programs are split among several different state agencies;*
- 2. MQSA is a radiation protection program and typically resides in the same state agency as the state's x-ray program.*

*Under MQSA, states can sign contracts with FDA to perform inspections for FDA at facilities performing mammography. These contracts must be reviewed annually. In exchange, states are provided training, equipment (instruments and phantoms), and laptop computers for filing inspection reports. States also receive funds from the FDA for each inspection performed. State personnel inspect facilities against FDA's rules and in accordance with FDA's procedures. Inspection data are provided to FDA. FDA is responsible for enforcement and issuance of certificates for mammography facilities.*

The Working Group recognizes that there are many obstacles to implementing this Option; however, it has been presented as a program that has worked for other federal agencies and states. The Delegated Program option could be used to supplement the current Agreement State system and NRC's efforts to verify a consistent approach to regulating radioactive materials. For example, NRC could contract with states to perform inspections at VA hospitals or other federal jurisdictions. NRC would retain authority, but in essence, contract with the states to supplement NRC staff.

## Delegated Program

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### Advantages

One entity develops and publishes rules. Rules become more uniform across the country and the process is more streamlined. Likewise, greater consistency in training and interpretation of rules results. This especially benefits licensees with facilities in multiple jurisdictions. Those companies would hold a single NRC license for multiple locations in the U.S.

One entity has comprehensive understanding of the National Materials Program, and Congress and licensees may turn to the program when seeking the national perspective.

A Delegated Program provides an alternative solution to a funding problem states experience when they start their Agreement programs. States wishing to become Agreement States find it difficult to get personnel trained and programs in place once a letter of intent has been signed by their governor. States have historically requested funding or "seed money" to get their programs started. NRC has not provided such funding in the past. Under a delegated program contract for certain types of licensees, state personnel could be trained by NRC staff. This could also be used by NRC as a mechanism for encouraging states to develop regulatory programs.

### Disadvantages

Responsibility for public health and safety related to radiation control moves from state-level to federal-level. It is unlikely that states would voluntarily give its authority to a federal entity. States have no authority to regulate radioactive material within their borders unless delegated to them.

The number of states signing contracts may vary from year to year.

A single regulatory entity makes it more difficult to address regional needs.

Variability in licensing and inspection techniques will occur. Assessing federal reimbursement to states for resources used to implement delegated duties may vary. Variations occur based on the number and types of licensees and cost of living factors in different areas of the country.

## Delegated Program

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### 1. Roles and Responsibilities of NRC and States for Each Program Element

#### A. Performing Materials Licensing (including Sealed Source and Device Reviews, Low-level Radioactive Waste, Uranium Recovery, and Decommissioning)

##### States

States no longer have authority to license the use of radioactive materials within their borders. If a state participates in a delegated program for licensing, the state is required to evaluate applications in accordance with NRC's procedures. The state does not issue state licenses, but NRC licenses.

##### NRC

NRC has authority to license all uses of radioactive material in the U.S. NRC can delegate licensing activities to states that have requested to participate in such a program. This delegation may include the entire suite of licensing activities, or may apply only to certain types of licenses (such as specifically and generally licensed gauges).

It would not be cost effective to train staff in three different states to regulate low-level waste disposal; therefore, the NRC would probably not delegate these programs.

It would not be cost effective to train staff in four different states to regulate uranium recovery facilities; therefore, the NRC would probably not delegate these programs.

NRC may delegate monitoring of decommissioning activities and verification surveys at decommissioned sites; however, final approval of decommissioning is the responsibility of the NRC.

## Delegated Program

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### B. Performing Materials Inspections

#### States

States would no longer have authority to inspect the use of radioactive materials within their borders. If a state participates in a delegated program for inspection, the state must inspect according to NRC's procedures. The state would not have any enforcement authority.

#### NRC

NRC has the authority to inspect all uses of radioactive material in the U.S. NRC can delegate inspection activities to states. This delegation may include the entire suite of licensed activities, or may apply only to certain types of licensees (such as specifically and generally licensed gauges).

### C. Incidents/Allegations

#### States

Response to incidents would be dependent on delegated authority.

#### NRC

NRC may delegate the response to incidents within states, but would probably retain responsibility for responding to allegations.

### D. Materials Licensing Guidance, Inspection Guidance and Rulemaking

#### States

States would not be required or allowed to develop guidance or rules. If a state determined that guidance was needed, they must ask NRC to take action.

#### NRC

NRC would be responsible for developing and publishing licensing and inspection guidance and rules. NRC may wish to ask states for input on these products, based upon the state's experience.

## Delegated Program

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### E. Training, Qualifications and Experience Standards for Regulatory Personnel

#### States

Each state is responsible for tracking training their own staff. States must make sure that qualified individuals perform delegated activities under the contract.

#### NRC

Because NRC has authority to regulate the use of radioactive material, NRC must ensure staff has received adequate training. This includes NRC staff and staff in states with delegated duties as well.

### 2. What are the Roles/Responsibilities of NRC and States in the Current Federal/States Relationships?

This Option allows for any existing or future federal entity to run a National Materials Program. The entity is NRC for purposes of this comparison.

The roles of NRC and states changes from co-regulators to an employer/contractor relationship. NRC, as the federal entity, establishes regulation for the use, storage and transfer of radioactive material as well as guidance for licensees. NRC has responsibility for performing license reviews, issuing licenses and performing inspections. States or territories can "contract" with the NRC to perform license reviews and/or inspections for certain categories of licenses, according to NRC's procedures. NRC maintains enforcement authority. NRC collects fees from licensees. States receive training and funding to fulfill terms of the contract. NRC performs activities in states/jurisdictions that have not assumed delegated duties.

### 3. Are Statutory Changes Required for this Option?

The AEA would need to be revised to delete Agreement State program authority, and allow delegated program authority. States may need to modify their legislation in order to participate in a delegated program. NRC currently regulates only AEA material, but this Option requires changes to the AEA, and the scope of radioactive materials covered by the AEA could be modified at that time to include NARM.

### 4. What Coordination is Required?

Coordination would be needed to make sure states are meeting contract obligations and to provide instruction to NRC Regions and delegated states.

## Delegated Program

### 5. Resources Needed and Who Pays?

Licensees would pay fees that would offset the expenses in states with delegated duties. States could try to supplement their contracts by charging fees for duties such as incident response or performing additional inspections when there has been a problem at a facility.

The following table compares the current NRC program resources and NRC resources to be expended if all 50 states participate in a Delegated Program. The estimate assumes 1) states would be responsible for implementing NRC's licensing, inspection and incident response functions, and 2) NRC does not delegate regulatory activities at uranium recovery and low-level radioactive waste facilities.

**Figure 3.5 - NRC Resources for Current Program and Delegated Program**

Activity	Current Program Costs* \$ in millions	Current Program Costs* FTE	Delegated Program \$ in millions	Delegated Program FTE
NMSS, Regions	\$ 26.6	197	\$ 38.7	149
Direct Support**	\$ 10.0	63	\$ 18.8	143
Agency Overhead***	\$ 18.4	76	\$ 18.5	76
<b>Total</b>	<b>\$ 55.0</b>	<b>336</b>	<b>\$ 76.0</b>	<b>368</b>

Source: NRC's FY 2001 budget - These resource estimates are based upon NRC's FY 2001 budget, and are used as the base case for comparison of the various options throughout this section

\* Costs are the sum of contract support, travel costs and staff salaries and benefits.

\*\* These resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.

\*\*\* These include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

The changes in FTE from the Current Program in NMSS and the regions are a result of NRC's decreased effort in licensing and inspection activities. The resources necessary to write rules, guidance and procedures would remain the same as the Current Program. Additional resources would be necessary to administer the contracts associated with a delegated program.

## **Delegated Program**

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### **6. Accountability**

NRC would be responsible for making sure that all delegated programs were functioning as specified in contracts and that the "national" program was meeting the NRC's strategic goals.

### **7. Program Assessment**

Program reviews are conducted and frequency corresponds with the contract expiration date. If a program has not performed its duties according to the terms of the contract, the contract will not be renewed. There may be some provisions for terminating a contract if there are significant health and safety concerns.

### **8. Program Gaps**

If the AEA is amended to incorporate discrete NARM, as recommended by the Working Group and stakeholders, the Working Group does not envision any program gaps other than the regulation of diffuse naturally-occurring radioactive material.

## Single Regulatory Agency

**A Single Regulatory Authority, NRC, becomes the pre-eminent regulator of radioactive materials covered under the Atomic Energy Act. NRC seeks authority to regulate NARM materials in discrete form for a more comprehensive radiation regulatory program as stakeholders suggested in a meeting in Arlington, Texas.**

What are the roles/responsibilities of the NRC for each program element?	NRC reassumes regulatory responsibility in former Agreement States and assumes the role as the single regulator for all radioactive material. This Option assumes NRC obtains authority for NARM. NRC interacts primarily only with its licensees and stakeholders. There would be few direct interactions with states or state organizations over regulatory issues.
What are the roles/responsibilities of an Agreement State for each program element?	States have no regulatory responsibility for radioactive materials. They retain responsibility for regulating other sources of ionizing radiation.
Are statutory changes required?	Yes, the Agreement State Program must be eliminated from the AEA. Agreements need to be abrogated on a individual basis. NRC would need NARM authority to establish a comprehensive national materials program. States need to enact legislation to exclude AEA and NARM, yet retain authority for other sources of radiation.
What coordination is required?	An extensive federal and state effort is necessary to revise AEA. Substantial stakeholder involvement is required at both state and federal levels. An equally extensive effort is needed to abrogate each agreement under revised statutes and to convert state licenses to NRC licenses.
What resources are needed (federal and state)? Who would pay?	Present and future NRC licensees pay all program costs. The significant heavy cost of conversion becomes an "equity issue" for present NRC licensees. New licensees coming under NRC's regulatory authority could object to paying for the transition. NRC would also fully fund infrastructure to support its national program. States pay nothing, except for their costs to change legislation and terminate agreements.
Accountability	NRC accountability is similar to the Current Program. State accountability is similar to the Current Program, but only for diffuse naturally-occurring radioactive material.
Program Assessment	NRC needs to develop a new assessment program that would focus its evaluation on regional activities. IMPEP could be used as a model.
Program Gaps	AEA would need to be amended to include NARM. The only gap regarding radioactive materials would be diffuse NORM.

## Single Regulatory Agency

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### Advantages

If NRC has authority to regulate NARM, it provides an immediate framework for a centralized National Materials Program.

In a centralized operation, the rulemaking, policy, guidance and decision making process would be less encumbered. NRC would not have to rely upon, or ask for states opinions or take into account their regulatory experience when conducting business. NRC would only have to be responsive to stakeholders, standards development organizations and the public.

While little direct savings would accrue from this "improved" process, states would no longer participate, thus saving some time and effort. The issue of compatibility of rules would be moot; the only applicable rules would be those enacted by NRC.

### Disadvantages

To maintain an effective program and provide reasonable service to its stakeholders, NRC would need to redesign its existing structure.

NRC will take regulatory authority over approximately 15,000 licensees in the continental United States. In the mid-1990's, when NRC licensed approximately 6- 7,000 licensees, NRC decreased from five Regions to four to accommodate a changing business environment. As the Single Regulatory Agency, NRC must devise ways to service the additional territory and licensees from the former Agreement States. Agreement States currently regulate about three times as many licensees as NRC (15,000 to 5,000). One option for NRC is to increase the number of Regional offices. Another set of options, such as the use of satellite offices, or extensive work-at-home arrangements could be employed. Another idea, expressed by one stakeholder, would be to establish an NRC office in each State. The administrative costs for such a large organization would be much more expensive than the Current Program.

NRC would be faced with an immediate need to increase the size of its management, professional and support staff and infrastructure. Cost of initial efforts are expected to be proportional to the number of existing licensees.

The extensive Agreement State knowledge base would be quickly dissipated and lost with this Option.

## Single Regulatory Agency

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### Advantages - cont'd

A stakeholder pointed out that having a single license issued by a national entity would be preferable to the present system where a licensee has to have several licenses or have reciprocity recognition from different regulators. Manufacturers and distributors of sources and devices expect positive benefits because only one license would be required.

Reconsolidating NRC's regulatory authority and including NARM could improve a discordant business environment, especially businesses whose activities cross regulatory boundaries.

Stakeholders believe that the cost of business would be lower and more consistent if radiation regulatory activities were administered by a single regulator. On average, the costs to licensees would decrease due to an economy of scale. Costs of a reunified regulatory program would be shared by a much larger licensee base.

Additional cost savings would be realized only for states in the areas of rulemaking, guidance and policy because single, national rules, guidance and policy would need to be developed instead of those for 32 individual states.

### Disadvantages - cont'd

Some state programs are heavily subsidized by state general revenue funds. If the cost of a reunified program is passed on to those licensees, they may actually see an increase in fees.

## **Single Regulatory Agency**

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### **1. Roles and Responsibilities of NRC and States for Each Program Element**

Under this Option, only NRC has responsibility for addressing radiation protection program elements. There would be no change from NRC's current procedures, but there would be significant changes to the size of NRC's program.

NRC's role and responsibility remains the same as it was prior to the amendment of the AEA that permitted the development of Agreement States. Currently, NRC has relinquished its regulatory authority in 32 states. The change from the current program to a Single Regulatory Agency could be made voluntarily or required by legislation.

### **2. Are Statutory Changes Required for this Option?**

A revision of the AEA to eliminate the Agreement State Program and for NRC to assume responsibility for regulating discrete NARM sources would be needed.

To terminate the Agreement State program through legislation, Congress would need to amend the AEA. NRC would abrogate the existing agreements, thus restoring NRC as the single regulator for AEA materials. Some states could object to any change to the AEA that would eliminate what they believe to be their highly successful state run radiation protection programs.

Although some states favor having NRC assume control over discrete NARM to further the development and consistency of a National Materials Program, this belief may not be universally held. Some Agreement States believe that they are already regulating both AEA and NARM in a consistent manner. What is needed, they believe, is for a more comprehensive process that would regulate similar risks from dissimilar materials in a like manner.

### **3. What Coordination is Required?**

To voluntarily reassume its role, NRC would cancel its existing agreement with each Agreement State, likely spending considerable time and funds explaining the need to reverse the current program. NRC would need to obtain some form of consensus among the states, business, and the public. Thereafter, a smooth transition would result only if all existing Agreement States would readily agree to abandon each of their agreements with NRC. Should one or more Agreement States disagree with NRC's proposal, legal action would be likely. An individual state or a group of states could sue to prevent NRC's proposed change in the Agreement State program. The result would be a period of disharmony not conducive to operating an effective regulatory program.

## Single Regulatory Agency

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### 4. Resources Needed and Who Pays?

NRC licensees will fully fund the program unless Congress authorizes greater "off fee base" funding for certain aspects of a National Materials Program. Former Agreement States will have no responsibility for operating or funding a regulatory program. Although costs of the larger, nationalized program would be shared among the larger licensee base, it is unlikely that the licensees would see a marked decrease in fees from the present level. It's equally likely that fees may increase substantially. Increases would be needed to increase infrastructure and staffing, train more staff in licensing and inspection, increase management to support the increase in staff, and the increased costs for renting, leasing or buying more facilities to support a presence throughout the U.S. These increases could be necessary to support NRC in assuming authority for licensees formerly under Agreement State control.

For former Agreement State licensees, little change may occur because states tend to include NARM and AEA materials under a single license.

A Single Regulatory Agency assumes that NRC would implement a program sufficient to regulate all radioactive material in the US. The total number of AEA materials licenses in the US is approximately 20,000. NRC's current resources in the materials arena would need to increase fourfold. Costs for regulating discrete NARM have not been included in these estimates because the bulk of the impact is in the increase in number of licenses from Agreement States, and those licenses treat NARM and AEA material in a similar manner. NRC resource implications are given in Figure 3.6 on the following page.

## Single Regulatory Agency

Figure 3.6 - NRC Resources for Current Program and Single Regulatory Entity

Activity	Current Costs* \$ in million	Current Costs* FTE	Single Regulatory Costs* \$ in million	Single Regulatory Costs* FTE
NMSS, Regions	\$ 26.6	197	\$ 57.4	456
Direct Support**	\$ 10.0	63	\$ 14.8	120
Agency Overhead***	\$ 18.4	76	\$ 40.8	168
Total	\$ 55.0	336	\$113.0	744

- \* These resource estimates are based on NRC's FY 2001 budget and used as the base case for comparison of the various options throughout this section. Costs are the sum of contract support, travel costs and staff salaries and benefits.
- \*\* Resources include State and Tribal Programs, Materials Research, Incident Response, Enforcement, Investigations, Legal Advice, and Adjudication.
- \*\*\* Resources include indirect resources providing policy, financial, administrative, information technology infrastructure, personnel support, and physical plant support (rent, utilities, building maintenance, etc.).

### 5. Accountability

NRC would be accountable for all radioactive material uses in the United States. States would only be accountable for other ionizing radiation.

### 6. Program Assessment

Agreement States would not exist as NRC assumed its prior authority; therefore, program assessment is not required under this option. NRC may, if it chooses to do so, institute a self-assessment of programs and quality assurance to assure consistency between its offices nationwide.

### 7. Program Gaps

If NRC assumes responsibility for NARM, most gaps in a National Materials Program are eliminated.

## **SECTION IV**

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**The Working Group recommends a structural option for implementing a National Materials Program and four components for a National Materials Program.**

**Adopt the Alliance Option  
and Develop an Implementation Plan**

**and**

**Use Centers of Expertise  
Seek Authority to Regulate NARM  
Maintain an Information Infrastructure  
Create a Standing Compatibility Committee**

## **Recommendations for a National Materials Program**

*The Working Group recommends the Alliance as a structure for a National Materials Program.*

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### **Adopt the Alliance Option and Develop an Implementation Plan**

The Working Group recommends that the Commission adopt the Alliance Option as a sound basis for achieving its strategic goals, maintaining a national presence, and meeting the objectives of a National Materials Program as the NRC enters into more agreements with states. The Alliance Option is a flexible structure that permits "task organization" of national resources and expertise to quickly address any future health and safety issue.

An Implementation Plan should also be developed and used to ensure that the Commission's recommendations are fully enacted. Due to the significant changes involved in using the Alliance Option as the approach to a National Materials Program, the Commission will need to give the staff strong, clear direction for implementation. The Working Group recommends development of an Implementation Plan, regardless of the option the Commission chooses.

## The Alliance as a National Materials Program

*The Working Group recommends the Alliance Option based on numerous advantages, cost savings, and enhanced ability to share expertise.*

### Advantages and Justifications for the Alliance Option

- best suited for essential development of common goals and objectives, joint decision-making, shared resources and responsibilities
- greatest potential to achieve on a national level the goals in NRC's strategic plan
- highest rank in the analytical criteria used to evaluate the six options for a National Materials Program

### Recommendation

The Working Group has determined through its evaluations that the Alliance Option provides the most assurances for meeting the needs of NRC, states, and a National Materials Program.

### Strengths of the Alliance Option

The Alliance takes advantage of the many positive features found in the current program, which already enjoys a high level of familiarity and acceptance among regulators, licensees, stakeholders, and the public.

The Alliance Option leverages the collective experience and expertise of all stakeholders to accomplish the common goals, meet national priorities and schedules, and maintain an infrastructure essential to protect public health and safety.

The Alliance Option's flexible structure permits "task organization" of national resources and expertise to quickly address any future health and safety issue.

### Rank Compared to Other Options

In order to assure it did not bias its recommendations, the Working Group also used a well proven analytical method, the relative value decision matrix, to evaluate the six options presented in Section III. The matrix helps ensure bias and subjectivity are minimized in the decision process; it is widely used in business and the military.

The results of the matrix analysis indicate that the Alliance Option is most consistent with the objectives of a National Materials Program. See Figure 4.1 on the following page. A description of the decision matrix and how it operates are found in Appendix D.

## Relative Value Decision Matrix

*The Working Group used the matrix to further analyze its recommendations.*

The relative value decision matrix technique was used to mathematically analyze the options considered by the Working Group. This tool objectively analyzes the six options considered in Section III and reduces the subjectivity errors that occur when several options are simultaneously considered. The eight Evaluation Criteria are based on NRC's strategic goals, and the objectives of a National Materials Program previously identified by the Working Group.

**Figure 4.1 - Evaluation of National Materials Program Options**

Weight	4.68	2.06	1.04	1.04	1.04	1.04	1.00	1.04	Total
Evaluation Criteria	Maintains Safety	Optimize Resources	Promote Consensus	Account for Individual Program Needs	Flexibility	Exchange of Information	Harmonize Regulatory Approaches	Public Confidence	
Options									
Current Program (Base Case)	4	3	2	3	3	4	4	2	44
Minimum NRC Involvement	5	5	3	4	4	5.5	5	4	60
Independent States	6	6	5	1	1	5.5	6	5.5	65
Delegated Program	2	4	5	5	5	2	2	3	41
Alliance	2	1.5	1	2	2	3	2	1	24
Single Regulatory Agency	2	1.5	5	6	6	1	2	5.5	39

Relative Values Matrix (Less is Better)

Consistency Ratio = 99.28%

## Costs Savings with the Alliance Option

*The Working Group believes the Alliance Option will best use existing resources.*

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**Two NRC factors greatly influence costs in the current materials program:**

- **policy decisions**
- **degree or intensity of how policies are implemented**

### **Cost Savings**

The Working Group believes that with the Alliance Option, some cost savings will be realized for both NRC and Agreement States because it creates an improved process for rulemaking, rule reviews, compatibility determinations, and developing common regulatory products. Actual savings depend on the level of participation in the development of regulatory products.

The Alliance Option spreads the responsibility for determining the direction and focus of a National Materials Program among a wider group of participants. This provides two advantages which should result in cost savings. The Alliance allows participants to:

1. affect policy decisions that direct the National Materials Program, and
2. control the degree or intensity of individual program participation.

The Alliance also offers the flexibility to use existing resources in a more focused manner. The Alliance Option offers the best opportunity for NRC to economically continue as a significant player in a National Materials Program as more and more states become Agreement States.

## Assumptions Regarding the Alliance Option

*The Working Group recommends the Alliance Option with the assumption that expertise and responsibilities will shift.*

**The Alliance Option is a necessary and practical solution to the issues NRC faces with the continued growth in the number of Agreement States and declining licensee base.**

### Assumptions Necessary for Success

1. States develop and maintain a level of technical and regulatory expertise at least equal to, or greater than, that of NRC.
2. The federal government transfers regulatory authority to states competent in developing and organizing programs that are adequate to protect workers and the public.

These assumption are in keeping with the trend that began in 1971 with the number of licensees regulated by Agreement States exceeding the number of NRC licensees. As states gain expertise and statutory authority, the federal agency transfers authority.

As more states become Agreement States, states will regulate even larger numbers of licensees. This will require states to develop and maintain more regulatory and technical expertise to meet emerging technologies. With fewer licensees and fewer types of uses of radioactive materials, it may become difficult for NRC to maintain an awareness of current and emerging technologies and to develop appropriate regulatory responses unless it significantly changes the way it interfaces with its stakeholders, the states, and the public. The experience base in many technical areas now lies outside NRC.

The Alliance Option offers the prospect of leveraging NRC's program by joining in a continuing collaborative process with other regulators. The process would jointly establish national priorities and agendas, share resources, and develop common regulatory products.

# Recommendations for a National Materials Program

*The Working Group recommends these components of a National Materials Program for Commission consideration.*

The Working Group identified four components of a National Materials Program it believes the Commission should adopt. The Alliance is the structural option that most effectively incorporates these four components. However, the Working Group believes that these components should be adopted regardless of the option or combination of options the Commission chooses for the structure of the National Materials Program. Each of these components is discussed in greater detail in Section V.

**Use Centers of Expertise**

This concept optimizes resources of federal, state, professional, and industrial organizations and reduces duplicate efforts.

**Seek Authority to Regulate NARM**

Radioactive material is not regulated consistently on a national basis. The Working Group is aware that NRC is currently evaluating the issues involved with seeking authority to regulate NARM. In order to create consistency nationwide, the AEA would ideally authorize the regulation of NARM.

**Maintain an Information Infrastructure**

An information infrastructure would maximize the sharing of information and resources. Such a clearinghouse would consolidate resources, reduce duplication, promote Centers of Expertise, and provide alternative resources to stakeholders in a timely manner.

**Create a Standing Compatibility Committee**

The Standing Compatibility Committee would consist of individuals who would not be directly involved in the development of a rule. The compatibility recommendations to the Commission would then represent a broader range of input and would provide consistency in designating compatibility levels across the range of rules.

## **SECTION V**

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**In Section V, the Working Group explains in further detail the four components of the National Materials Program recommended in Section IV. These components are most effectively incorporated in the Alliance Option, but should be considered regardless of the option or combination of options chosen for a National Materials Program.**

- **Use of Centers of Expertise**
- **Seek Authority to Regulate NARM**
- **Maintain an Information Infrastructure**
- **Create a Standing Compatibility Committee**

## Use Centers of Expertise

*Using Centers of Expertise optimizes resources.*

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### **Centers of Expertise**

Regardless of whether or not the Alliance Option is adopted, the Centers of Expertise concept should be implemented in a National Materials Program.

### **Centers of Expertise**

Centers of Expertise are an integral component of the recommended Alliance Option for the National Materials Program. The Centers of Expertise concept optimizes resources of federal, state, professional, and industrial organizations and reduces duplicate efforts.

Some Agreement States and NRC regions have, over time, developed considerable experience and expertise with specific uses of radioactive materials. Examples of areas of expertise include well logging, industrial radiography, positron emission tomography, and intravascular brachytherapy. Agreement States and NRC regions that have developed expertise in specific uses should be identified and used as a resource by other regulatory programs. These Centers of Expertise may change over time as others develop expertise.

A specific process for identifying and utilizing Centers of Expertise should be developed in the implementation plan for the National Materials Program.

## Seek Authority to Regulate NARM

*NRC should seek legislative authority to regulate discrete sources of NARM.*

### **Inconsistency in NARM Regulation**

A fragmented regulatory scheme treats similar radioactive materials (and in some cases the same radioisotope) differently based on how the material is produced. Wide disparities in the way materials are regulated exist among states, although the risks of the materials are the same. This is inconsistent with the concept and goals of a National Materials Program.

### **Regulation of NARM**

The Working Group recommends that the NRC seek legislative authority to regulate discrete sources of NARM. This does not include diffuse naturally-occurring radioactive material.

### **Variations in Regulation of NARM**

The Working Group recognizes that radioactive material is not regulated consistently on a national basis. NARM oversight varies among states, and in some states, the oversight is not based on risk.

Some non-Agreement States license and inspect NARM similarly to the oversight provided by NRC and Agreement States.

Some non-Agreement States only register NARM sources and may not conduct any inspections.

NRC regulation of NARM would meet three of NRC's strategic goals by:

- maintaining public health and safety through establishment of a regulatory oversight framework that ensures that materials licensees continue to conduct activities involving the use of radioactive materials in a safe manner;
- improving the effectiveness of regulatory programs nationwide; and
- reducing unnecessary regulatory burden.

The Working Group understands that NRC is currently looking into the issue of regulation of NARM, and believes in an ideal situation, the AEA would authorize the regulation of all NARM. However, it may be more practical for NRC to seek authority for only discrete NARM sources.

## Seek Authority to Regulate NARM - cont'd

*Regulation of NARM by NRC would require startup resources and ongoing costs, both believed to be minor in relation to the overall program.*

**If granted statutory authority, NRC could begin to regulate NARM without significant change to existing rules and guidance.**

**The Chair of the OAS informally asked Agreement State and non-Agreement State managers and staff about their opinions on NRC licensing NARM.**

**Of those program managers who responded, most favored regulation of NARM by NRC, but were concerned about compatibility issues.**

### **Resources**

The Working Group considered resources when determining the relative value of regulating NARM. See Appendix C. Regulation of NARM by NRC would require startup resources, but the Working Group does not believe these will be significant. The ongoing cost of regulating discrete NARM is predicted to be minor in relation to the overall program, as is the case in Agreement States.

### **Impacts on NRC**

The Working Group believes regulating NARM will have limited impacts on NRC.

NRC for the most part already licenses the same type of activities with AEA materials. For uses of radioactive materials for which NRC does not have a history, they can look to the Centers of Expertise – those states that already license NARM.

### **Cost Savings**

There would be a potential resource saving for some licensees and for some non-Agreement States, as most NARM licensees also have an NRC license. Elimination of dual regulation would result in savings to the licensee and to the state. A consequence of including NARM in the materials regulated by NRC could be the dissolution of some non-Agreement State radioactive materials programs unless the option encouraged or forced non-Agreement States to seek Agreement State status.

### **NARM in the National Materials Program**

The Working Group recognizes that not all states will want NRC to seek this new authority. However, a true National Materials Program must be based on risk and must maintain safety, improve effectiveness, and reduce regulatory burdens. A nationally uniform process that regulates similar risks from similar radioactive materials in a consistent manner will best assure this.

## Maintain an Information Infrastructure

***Mechanisms for an Information Infrastructure and a new Working Group are recommended.***

The National Materials Program Working Group recommends that a new Working Group be established. The task of this group would be to further define the Information Infrastructure necessary to support the existing nationwide regulatory structure program or any option or combination of options the Commission chooses.

**Create an Information Infrastructure that would consolidate resources, reduce duplication, promote Centers of Expertise, and provide alternative resources to stakeholders in a timely manner.**

**Develop and share on-line information and resources essential to a National Materials Program.**

### **Information Infrastructure**

An Information Infrastructure, or clearinghouse, could include rules, guidance documents, forms, industry and professional standards, incidents and events (for tracking performance and identification of generic safety issues), numbers and types of licensees for regulatory agencies, sealed source and device registration sheets, escalated enforcement actions, certification, personnel directory information, services (waste brokers, recycling), program information, training, etc. The distribution can be either active, as in visiting a website, or passive, as when information is automatically distributed to users.

### **On-Line Resources**

Many regulatory agencies have statutes, rules, and other information on-line. Some states and NRC also have policies, procedures, and guidance on-line. CRCPD maintains lists of contacts for a wide variety of radiological assistance and technical information at its website. Professional organizations maintain on-line resources. NRC also maintains several specialized national databases on-line, such as the Nuclear Materials Events Database and the Sealed Source & Device Registry. Over time, experienced stakeholders have learned what information is available and where to locate it. No on-line mechanism exists to make it easy to identify, collect, access, or distribute relevant information from the many sources.

The Working Group suggests that NRC should continue to maintain and improve current on-line resources and should seek methods and technology to include, link to, or search other on-line resources and information. State radiation control programs should also link to the NRC's web pages.

**The working group believes that information requirements should be determined by consensus, with the NRC serving as a center of activity in the area of information distribution. NRC has demonstrated experience in developing and maintaining this vast amount of information on-line.**

## Create a Standing Compatibility Committee

*A Standing Compatibility Committee will improve the compatibility determination process.*

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### Recommendations:

- **A Standing Compatibility Committee should consist of individuals representing both NRC and Agreement States.**
- **Individuals should be specifically trained in making compatibility determinations based on the principles of the 1997 Compatibility Working Group.**
- **In order to maintain objectivity, Committee members should not be directly involved in the development of the particular rule being evaluated for compatibility designations.**
- **The Standing Compatibility Committee should establish the recommended compatibility levels using Management Directive 5.9.**
- **Committee recommendations for each rule should be presented to the Commission when the rule is presented.**

### Standing Compatibility Committee

A Standing Compatibility Committee could enhance the existing compatibility determination process. Such a committee offers these benefits:

- Membership would represent a broader range of input by including others in addition to NRC staff.
- Membership would provide consistency in designating compatibility levels across the range of rules.

This concept of a Standing Compatibility Committee is consistent with the objectives of a National Materials Program.

### Current Process

NRC determines compatibility using Management Directive 5.9, adopted in February 1998. This directive outlines the process by which compatibility recommendations are currently made. Unless statutes are changed, the Commission will continue to have responsibility to establish compatibility for rules. Beginning in 1995, a Compatibility Working Group of Agreement State and NRC representatives evaluated the level of compatibility of NRC rules. Most states believed the results of this compatibility review were valuable. However, since that time, NRC has been making compatibility decisions, with some disagreement between NRC and states resulting.

## Create a Standing Compatibility Committee - cont'd

*A Standing Compatibility Committee will provide a broader range of input, consistency in designating compatibility levels, and increased objectivity.*

Criteria exist for determining compatibility requirements. However, states believe that the criteria have been misapplied in some instances. A Standing Compatibility Committee could remedy this situation.

Under the Alliance Option, rules may be developed by Centers of Expertise. These centers may consist primarily or solely of Agreement State and/or non-Agreement State staff members. A Standing Compatibility Committee would provide consistency in compatibility determinations.

### **Disagreements Concerning Compatibility**

Some states believe the understandings and the intent of the compatibility review group have not been strictly followed. They believe that NRC has inadvertently misapplied the intent of Management Directive 5.9. This could occur, for instance, if an individual who drafted a rule elevated the compatibility level for that rule beyond the level an objective and impartial reviewer would designate.

Some in the Agreement States believe the misapplications of the intent of Management Directive 5.9 are demonstrated by the excessive use of compatibility category H&S (Health and Safety). A number of rules that otherwise have a compatibility category of D have been also designated as H&S. This designation then requires the Agreement States to adopt a rule they might otherwise not have a need to adopt. The following rules in 10 CFR are offered as examples:

- 20.1101(b)
- 20.1501(a)(2)(i)
- 20.1502
- 20.1906(d)

### **Benefits**

A standing compatibility committee would serve to minimize disagreement and would optimize resources by providing consistency.

## **Section VI**

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**In Section VI, the Working Group specifically responds to each of the six directives from SECY-99-250.**

## Responses to SECY-99-250 Directives

*SECY-99-250 directed the Working Group to respond to six issues.*

When the Commission established the National Materials Program Working Group in SECY-99-250, it indicated that the following six issues were key to defining and implementing future state and federal roles under a National Materials Program and should be addressed by the Working Group's report. The Working Group's response to each of the directives follows.

### 1. Development of an overall program mission statement with defined top level goals and objectives.

Mission            The mission of a National Materials Program is to provide a coherent national framework for the regulation of hazards associated with radioactive material.

Goal                Protection of public health and safety while effectively using regulatory resources.

Objectives

- Optimize resources of federal, state, professional, and industrial organizations
- Account for individual agency needs and abilities
- Promote consensus on regulatory priorities
- Promote consistent exchange of information
- Harmonize regulatory approaches
- Recognize state and federal needs for flexibility

### 2. Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including OAS and CRCPD.

The roles and responsibilities of NRC, Agreement States, and other organizations will vary depending on the option or combination of options chosen by the Commission.

Under the recommended Alliance Option, NRC and Agreement States will function as partners. The roles and responsibilities of NRC and states will be based on their program needs and expertise. There would be no changes to legal responsibilities, except for the acquisition by NRC of the authority to regulate discrete NARM.

Adoption of the Alliance Option could serve as the framework for participation and involvement of other stakeholders, including OAS, CRCPD, HPS, and standards developing organizations.

## Responses to SECY-99-250 Directives - cont'd

*SECY-99-250 directed the Working Group to respond to six issues.*

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### **3. Delineation of the scope of activities to be covered by the program and the need for statutory changes at both state and federal levels.**

In order to establish a comprehensive national regulatory program, discrete NARM would be regulated similarly to AEA materials, which would require statutory authorization.

Under an Alliance, the scope of types of activities performed by the NRC and states would remain essentially the same, but the intensity of those activities may vary.

### **4. Establishment of formal program coordination mechanisms.**

An Alliance consists of regulatory decision-makers from state and NRC program managers, an administrative core to coordinate and provide logistical support, and stakeholders to provide information and support to the Alliance.

The Alliance would be a structure through which national program goals and objectives are established and resources are coordinated to implement those goals and objectives.

### **5. Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.**

The Integrated Materials Performance Evaluation Program (IMPEP), which is designed to assess individual regulatory programs, should be retained.

In addition, the Alliance should develop a National Materials Program assessment process using IMPEP-type principals to evaluate at least the following nationwide program indicators.

- Meet strategic health and safety goals
- Decrease time to develop regulatory products
- Increase participation by state programs in development of regulatory products
- Decrease the time for implementation of rules nationwide
- Decrease resources necessary for development of regulatory products
- Evaluate participation by licensees, stakeholders and other federal agencies in the development of regulatory products
- Maintain an adequate Information Infrastructure.

## Responses to SECY-99-250 Directives - cont'd

*SECY-99-250 directed the Working Group to respond to six issues.*

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### **6. Provision/budgeting of resources at both state and federal levels.**

Resource implications for NRC are included in the discussion of the Alliance Option in Section III. The resource needs are dependent upon the intensity of NRC's involvement in a National Materials Program. Overall, an Alliance would provide for better utilization of existing resources at both the state and federal level.

# National Materials Program

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## Appendices



**Final Report of the Working Group**

**SECY 99-250**

**Volume II**

**May 2001**

# National Materials Program

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## Appendices



**Final Report of the Working Group**

**SECY 99-250**

**Volume II**

**May 2001**

# National Materials Program Working Group Report

examines

- *impacts of increasing number of Agreement States*
- *six options for a National Materials Program structure*

and

- *the following six issues as specified in SECY-99-250*

**Development of an overall program mission statement with defined top level goals and objectives.**

**Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc.**

**Delineation of the scope of activities to be covered by the program and the need for statutory changes at both state and federal levels.**

**Establishment of formal program coordination mechanisms.**

**Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.**

**Provision/budgeting of resources at both state and federal levels.**

# National Materials Program

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## **SECTION VII**

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### **Appendices**

**Section VII contains the reference materials and detailed appendices supporting the explanations in the text of the report.**

## APPENDIX A

## Acronyms Appearing in the Appendices

AEA	Atomic Energy Act	NARM	Naturally Occurring and Accelerator Produced Radioactive Material
AEC	Atomic Energy Commission	NAS	National Academy of Sciences
AMA	American Medical Association	NCRP	National Council on Radiation Protection
ANSI	American National Standards Institute	NEI	Nuclear Energy Institute
AS	Agreement States	NERHC	New England Radiological Health Committee
ASME	American Society of Mechanical Engineering	NESHAPS	National Emission Standards for Hazardous Air Pollutants
ANSI	American National Standards Institute	NIST	National Institute of Standards and Testing
ASNT	American Society of Nondestructive Testing	NMA	National Mining Association
CDC	Centers for Disease Control	NMED	Nuclear Materials Events Database
CRCPD	Conference of Radiation Control Program Directors, Inc.	NMP	National Materials Program
DOE	U.S. Department of Energy	NMPWG	National Materials Program Working Group
DOI	U.S. Department of Interior	NMSS	NRC Office of Nuclear Materials Safety and Safeguards
DOL	U.S. Department of Labor	NORM	Naturally Occurring Radioactive Material
DOT	U.S. Department of Transportation	NOV	Notice of Violation
EDO	NRC Executive Director of Operations	NRC	U.S. Nuclear Regulatory Commission
EPA	U.S. Environmental Protection Agency	OAS	Organization of Agreement States
FDA	U.S. Food and Drug Administration	OGC	NRC Office of General Counsel
FTE	Full-Time Equivalent	OMB	Office of Management and Budget
HPS	Health Physics Society	OSHA	U.S. Occupational Safety and Health Administration
HQ	NRC Headquarters	OSTP	NRC Office of State and Tribal Programs
IAEA	International Atomic Energy Agency	PET	Positron Emission Tomography
IMC	Inspection Manual Chapter	RSO	Radiation Safety Officer
IMNS	NRC Division of Industrial and Medical Nuclear Safety	SDO	Standards Developing Organization
IMPEP	Integrated Materials Performance Evaluation Program	SNM	Society of Nuclear Medicine
ICRP	International Commission on Radiological Protection	SSRCR	Suggested State Regulations for Control of Radiation
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual	TENORM	Technologically Enhanced Naturally Occurring Radioactive Material
MQSA	Mammography Quality Standards Act		
MSHA	U.S. Mine Safety and Health Administration		

## **Appendices**

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- A. Directives and References**  
This subsection provides documents that are background materials.
- B. Working Group Interactions and Communications**  
This subsection describes in depth the stakeholder outreach activities of the Working Group. Comments and responses are summarized.
- C. Evaluation of Program Elements**  
This subsection gives in depth information about program elements and suggested alternatives.
- D. Relative Decision Matrix**  
This subsection explains the relative decision matrix technique.

## **A. Directives and References**

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- **National Materials Program Working Group Charter**
- **SECY-99-250**
- **Section 274 of the Atomic Energy Act**

## APPENDIX A

# National Materials Program Working Group Charter

NRC formed a working group to provide the Commission with options for maintaining an infrastructure of supporting rules, guidance and other program elements needed for the nationwide materials program considering the anticipated increase in the number of Agreement States. The working group is composed of representatives of state governments and NRC. The Working Group will produce a report for the Commission's consideration.

### The Working Group Mission

The mission is to develop options for the Commission's consideration for creating a National Materials Program that will implement the following philosophy:

*To create a true partnership of NRC and states that will ensure protection of public health, safety, and the environment while:*

- *optimizing resources of federal, state, professional and industrial organizations;*
- *accounting for individual agency needs and abilities;*
- *promoting consensus on regulatory priorities;*
- *promoting consistent exchange of information; and*
- *harmonizing regulatory approaches while recognizing state and federal needs for flexibility.*

To accomplish the mission, the working group will consider the following issues:

1. the continuing trend for states to assume authority for the regulation of radioactive materials;
2. the potential impact of this trend on maintaining the infrastructure of the existing state and federal regulatory programs in the current fiscal environment and the increased fee burden on a decreasing number of NRC licensees to support generic activities;
3. the roles and legal responsibilities of NRC, Agreement States, Organization of Agreement States, Conference of Radiation Control Program Directors, Inc., and other organizations;
4. the need for statutory changes in federal and state programs for a National Materials Program;
5. the required elements and scope of activities in a materials regulatory program such as licensing, inspection, enforcement, training, event reporting, emergency response and program support activities including developing licensing and inspection guidance, developing program policy and guidance, developing standard review plans, providing laboratory support, and rulemaking activities;
6. the assessment process and performance indicators that could be used to measure the performance of a National Materials Program considering the current Integrated Materials Performance Evaluation Program process;
7. mechanisms for program coordination and program evolution;
8. the resource needs required for a National Materials Program and options for meeting those resource needs at both state and federal levels; and
9. accommodation of federal and state strategic performance goals and outcomes under a National Materials Program.

## APPENDIX A

## National Materials Program Secy-99-250

SECY-99-250

October 14, 1999

**FOR:** The Commissioners  
**FROM:** William D. Travers /s/ Executive Director for Operations  
**SUBJECT:** 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

**PURPOSE:**

To inform the Commission of the staff's plan to form a working group to address the impacts of the increased number of Agreement States and to provide advice to the Nuclear Regulatory Commission (NRC) on the National Materials Program.

**BACKGROUND:**

Presently, NRC exercises regulatory responsibility over about 5,310 material licensees. The 31 Agreement States regulate about 16,550 material licensees. Staff expects four additional States will become Agreement States by Fiscal Year (FY) 2003 and estimates that the number of NRC licensees will drop to approximately 4,000. At that time, the Agreement States will be regulating about 17,860 licenses. This shift in responsibility has significant implications for both NRC's materials program and the Agreement States. The process that NRC will use in the future to develop and maintain the infrastructure of regulations and supporting guidance applied by NRC and the Agreement States in their respective licensing and inspection programs should reflect this shift.

**DISCUSSION:**

Agreement State licenses currently comprise approximately 75% of the national total. With the forecast of four more States signing agreements by FY 2003, Agreement State licenses soon may comprise over 80% of the national total. In acknowledgment of this reallocation of licenses, NRC is placing more emphasis on program activities in support of the national infrastructure, particularly with emphasis on program activities such as rulemaking and guidance development activities, information technology systems, technical support, event follow-up, and Integrated Materials Performance Evaluation Program (IMPEP). These activities have a fee impact on an increasingly smaller number of NRC licenses.

Although NRC and Agreement State staff refer to a "National Materials Program," or use similar references (e.g., coherent nationwide effort), no clear definition has been established to define what is meant by a National Materials Program (e.g., its structure, characteristics, makeup, functions and resources). Staff believes the following six issues are key to defining and implementing future State and Federal roles under a National Materials Program and need to be addressed:

1. Development of an overall program mission statement with defined "top level" goals and objectives.
2. Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc., (CRCPD).
3. Delineation of the scope of activities to be covered by the program and the need for statutory changes at both State and Federal levels.
4. Establishment of formal program coordination mechanisms.
5. Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.
6. Provision/Budgeting of resources at both State and Federal levels.

**APPENDIX A****National Materials Program SECY-99-250 - cont'd**

To address the future of a National Materials Program, staff will establish a working group in accordance with Management Directive 5.3, "NRC and Agreement State Working Groups," to examine the impacts of the increased number of Agreement States and develop options for Commission consideration. The working group would examine potential frameworks through which the regulation of nuclear materials can be accomplished in the future when the size of Agreement State programs will collectively be significantly larger than that of NRC. The working group would need to address these six issues within the context of other related activities. For example, the group's actions must track with the appropriate materials arena goals, measures, and strategies from the new NRC Strategic Plan, once this new Plan is completed by NRC staff, reviewed by our stakeholders, and approved by the Commission. Regarding item 5, in establishing performance indicators and a program assessment process, the working group will need to be sensitive to the ramifications of its output on the indicators already in place in the IMPEP program. These IMPEP indicators were developed with significant input from NRC and the Agreement States, and have proven to be a highly-successful means by which we assess the technical adequacy, and consistency of our regional materials programs, and those in Agreement States.

The working group will be comprised of NRC, Agreement State, and CRCPD staff as follows:

Office of State Programs (OSP) - one representative (.5 FTE)  
Office of Nuclear Material Safety and Safeguards (NMSS) - one representative (.25 FTE)  
Office of the General Council (OGC) - one representative (.25 FTE)  
Regional Office - one representative (.25 FTE)  
CRCPD - one-two representatives (.25-.5 FTE)  
OAS - one-two representatives (.25-.5 FTE)

**RESOURCES:**

Staff believes agency resources of approximately 1.25 FTE, would be required to characterize and frame these issues for Commission review. This effort can be accommodated within the existing budget.

**COORDINATION:**

The Office of the General Counsel has no legal objections. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

William D. Travers  
Executive Director for Operations

## APPENDIX A

**Section 274 of the Atomic Energy Act****ATOMIC ENERGY ACT OF 1954****Sec. 274. Cooperation With States.****a. It is the purpose of this section—**

- (1) to recognize the interests of the States in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this Act of the States and the Commission with respect to the regulation of byproduct, source, and special nuclear materials;**
- (2) to recognize the need, and establish programs for cooperation between the States and the Commission with respect to control of radiation hazards associated with use of such materials;**
- (3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;**
- (4) to establish procedures and criteria for discontinuance of certain of the Commission's regulatory responsibilities with respect to byproduct, source, and special nuclear materials, and the assumption thereof by the States;**
- (5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and**
- (6) to recognize that, as the States improve their capabilities to regulate effectively such materials, additional legislation may be desirable.**

**b. Except as provided in subsection c., the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under Chapters 6, 7, and 8, and Section 161 of this Act, with respect to any one or more of the following materials within the State—**

- (1) byproduct materials as defined in section 11e.(1);**
- (2) byproduct materials as defined in section 11e.(2);**
- (3) source materials;**
- (4) special nuclear materials in quantities not sufficient to form a critical mass.**

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

c. No agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of—

- (1) the construction and operation of any production or utilization facility or any uranium enrichment facility;
- (2) the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- (3) the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;
- (4) the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission. The Commission shall also retain authority under any such agreement to make a determination that all applicable standards and requirements have been met prior to termination of a license for byproduct material, as defined in section 11e.(2).

Notwithstanding any agreement between the Commission and any State pursuant to subsection b., the Commission is authorized by rule, regulation, or order to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

d. The Commission shall enter into an agreement under subsection b. of this section with any State if—

- (1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and
- (2) the Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects compatible with the Commission's program for regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

e. (1) Before any agreement under subsection b. is signed by the Commission, the terms of the proposed agreement and of proposed exemptions pursuant to subsection f. shall be published once each week for four consecutive weeks in the Federal Register; and such opportunity for comment by interested persons on the proposed agreement and exemptions shall be allowed as the Commission determines by regulation or order to be appropriate.

**APPENDIX A****Section 274 of the Atomic Energy Act - cont'd**

(2) Each proposed agreement shall include the proposed effective date of such proposed agreement or exemptions. The agreement and exemptions shall be published in the Federal Register within thirty days after signature by the Commission and the Governor.

f. The Commission is authorized and directed, by regulation or order, to grant such exemptions from the licensing requirements contained in chapters 6, 7, and 8, and from its regulations applicable to licensees as the Commission finds necessary or appropriate to carry out any agreement entered into pursuant to subsection b. of this section.

g. The Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

h. There is hereby established a Federal Radiation Council, consisting of the Secretary of Health, Education, and Welfare, the Chairman of the Atomic Energy Commission, the Secretary of Defense, the Secretary of Commerce, the Secretary of Labor, or their designees, and such other members as shall be appointed by the President. The Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. The Special Assistant to the President for Science and Technology, or his designee, is authorized to attend meetings, participate in the deliberations of, and to advise the Council. The Chairman of the Council shall be designated by the President, from time to time, from among the members of the Council. The Council shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. The Council shall also perform such other functions as the President may assign to it by Executive order.

i. The Commission in carrying out its licensing and regulatory responsibilities under this Act is authorized to enter into agreements with any State, or group of States, to perform inspections or other functions on a cooperative basis as the Commission deems appropriate. The Commission is also authorized to provide training, with or without charge, to employees of, and such other assistance to, any such State or political subdivision thereof or group of States as the Commission deems appropriate. Any such provision or assistance by the Commission shall take into account the additional expenses that may be incurred by a State as a consequence of the State's entering into an agreement with the Commission pursuant to subsection b.

## APPENDIX A

**Section 274 of the Atomic Energy Act - cont'd**

- j.** (1) The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement under subsection b. has become effective, or upon request of the Governor of such State, may terminate or suspend all or part of its agreement with the State and reassert the licensing and regulatory authority vested in it under this Act, if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to insure compliance with the provisions of this section.
- (2) The Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission:
- (A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside of the State, and
  - (B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose.
- A temporary suspension under this paragraph shall remain in effect only for such time as the emergency situation exists and shall authorize the Commission to exercise its authority only to the extent necessary to contain or eliminate the danger.
- k.** Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.
- l.** With respect to each application for Commission license authorizing an activity as to which the Commission's authority is continued pursuant to subsection c., the Commission shall give prompt notice to the State or States in which the activity will be conducted of the filing of the license application; and shall afford reasonable opportunity for State representatives to offer evidence, interrogate witnesses, and advise the Commission as to the application without requiring such representatives to take a position for or against the granting of the application.
- m.** No agreement entered into under subsection b., and no exemption granted pursuant to subsection f., shall affect the authority of the Commission under subsection 161b. or i. to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material. For purposes of subsection 161i., activities covered by exemptions granted pursuant to subsection f. shall be deemed to constitute activities authorized pursuant to this Act; and special nuclear material acquired by any person pursuant to such an exemption shall be deemed to have been acquired pursuant to section 53.

## APPENDIX A

## Section 274 of the Atomic Energy Act - cont'd

n. As used in this section, the term "State" means any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia. As used in this section, the term "agreement" includes any amendment to any agreement.

o. In the licensing and regulation of byproduct material, as defined in section 11e. (2) of this Act, or of any activity which results in the production of byproduct material as so defined under an agreement entered into pursuant to subsection b., a State shall require—

(1) compliance with the requirements of subsection b. of section 83 (respecting ownership of byproduct material and land), and

(2) compliance with standards which shall be adopted by the State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose, including requirements and standards promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to sections 83, 84, and 275, and

(3) procedures which—

(A) in the case of licenses, provide procedures under State law which include—

(i) an opportunity, after public notice, for written comments and a public hearing, with a transcript,

(ii) an opportunity for cross examination, and

(iii) a written determination which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;

(B) in the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;

(C) require for each license which has a significant impact on the human environment a written analysis (which shall be available to the public before the commencement of any such proceedings) of the impact of such license, including any activities conducted pursuant thereto, on the environment, which analysis shall include—

(i) an assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such license;

(ii) an assessment of any impact on any waterway and groundwater resulting from such activities;

## APPENDIX A

**Section 274 of the Atomic Energy Act - cont'd**

(iii) consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and

(iv) consideration of the long-term impacts, including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined by section 11e.(2); and

(D) prohibit any major construction activity with respect to such material prior to complying with the provisions of subparagraph (C).

If any State under such agreement imposes upon any licensee any requirement for the payment of funds to such State for the reclamation or long-term maintenance and monitoring of such material, and if transfer to the United States of such material is required in accordance with section 83b. of this Act, such agreement shall be amended by the Commission to provide that such State shall transfer to the United States upon termination of the license issued to such licensee the total amount collected by such State from such licensee for such purpose. If such payments are required, they must be sufficient to ensure compliance with the standards established by the Commission pursuant to section 161x. of this Act. No State shall be required under paragraph (3) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission.

In adopting requirements pursuant to paragraph (2) of this subsection with respect to sites at which ores are processed primarily for their source material content or which are used for the disposal of byproduct material as defined in section 11e.(2), the State may adopt alternatives (including, where appropriate, site-specific alternatives) to the requirements adopted and enforced by the Commission for the same purpose if, after notice and opportunity for public hearing, the Commission determines that such alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with such sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by standards and requirements adopted and enforced by the Commission for the same purpose and any final standards promulgated by the Administrator of the Environmental Protection Agency in accordance with section 275. Such alternative State requirements may take into account local or regional conditions, including geology, topography, hydrology and meteorology.

## **B. Working Group Interactions and Communications**

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- **Communication Plan**
- **Meeting Schedule**
- **Meetings and Outreach Activities**
- **Questions and Comments from NRC Staff**
- **Responses to Stakeholder Questions NEHRC Meeting**
- **Input from Health Physics Society Focus Groups**
  - South Texas Chapter**
  - Atlanta Chapter**
  - New Jersey Chapter**

## APPENDIX B

# Communication Plan

### General Overview

*The NRC and States are in the process of developing options for a National Materials Program which will potentially offer opportunities for NRC, Agreement and non-Agreement States to work together in a more collaborative manner to achieve efficiencies in implementing our individual and joint responsibilities for regulating the use of radioactive materials and radiation sources. A Working Group has been formed, at the direction of the NRC Commission, to develop various options for implementing such a program. The Working Group has identified a need to provide information to various stakeholders on development of options that will be presented to the Commission and to seek feedback from its stakeholders during product development and once a draft product is completed. This communication plan provides an approach for meeting this need.*

### Objectives

1. *Provide information to stakeholders in a timely manner, as the product is developed*
2. *Create positive stakeholder perception by seeking feedback from stakeholders as products are developed and working in a collaborative manner with all stakeholders to develop recommendations for the Commission*
3. *Engage misconceptions, correct inaccurate information, and reduce uncertainty*
4. *Actively engage stakeholders at all levels by soliciting feedback and maintaining positive relationships*
5. *Identify issues involving a cultural transition of NRC, State and other stakeholders and seek feedback on how these issues can be addressed*
6. *Consider stakeholder comments in Working Group products*

### Stakeholders

- *NRC Staff: HQ, Various Program Offices, Regions*
- *Agreement and non-Agreement State Staff*
- *Other Regulatory Agencies: EPA, OSHA, DOT, FDA, DOE, DOL, MSHA, DOI*
- *Licensees*
- *The Public*
- *Industry Representatives: Manufacturers, Consultants, Professional Organizations (SNM, AMA, HPS, ASNT, SMA, NMA, NEI)*
- *Standards Organizations: NIST, ASME, ASNT, ANSI, ICRP, NCRP, IAEA*
- *OMB*
- *Congress and State legislatures*
- *Citizen and Environmental Groups*

**APPENDIX B****Communication Plan - cont'd**

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**Communication Tools and Opportunities**

- *NRC Web Site and Written Communications: OSTP/NMPWG site, NMSS Newsletter, Regional Web Sites or Newsletters, NR&C*
- *State Web Sites and Written Communications: Radrap, CRCPD Newsletter*
- *Federal Register*
- *Industry/Professional Written Communications: HPS Newsletter, ASNT Newsletter, Journal of Nuclear Medicine, etc.*
- *Industry and Professional Meetings: HPS, ASNT, SNM, etc.*
- *State/NRC Interface: CRCPD meeting/poster session, OAS meetings and conference calls, NERHC, NRC Counterpart Meetings*
- *Public Affairs Interface*
- *Pilot Projects: OAS tabletop exercise*
- *Senior Management Interface: EDO, Commissioner Technical Assistants, Senior Management Meeting, IMNS Director's Conference Calls, Commission Briefing*

**Message Development and Objectives**

- *Provide information on draft product, while in progress, to stakeholders and obtain feedback*
- *Distribute messages directly to all levels of stakeholders and encourage individual participation*
- *Consider stakeholder comments in developing Working Group products and provide feedback to stakeholders regarding resolution or outcome*
- *Provide consistent messages by various communicators*
- *Provide a planned/structured communication approach corresponding to the various stages of product development; the communication plan should account for the challenges associated with the scope and complexity of the project at various stages in development*
- *Account for the different perspectives of and needs for communication with external stakeholders*

## APPENDIX B

## Communication Plan - cont'd

**Key Messages**

- *Maintain safety by establishing a regulatory oversight framework that ensures that materials licensees continue to conduct activities involving use of radioactive materials and radiation sources in a safe manner. The States and NRC have done an excellent job in regulating materials users; however, due to the continued shift in regulatory oversight responsibilities and authorities from NRC to Agreement States, a more collaborative approach is needed. This approach should seek to balance use of resources between the States and NRC and distribute the resource burden more equitably between Agreement State and NRC licensees. Maintaining regulatory programs that are adequate to protect public health and safety is a priority in evaluating potential changes.*
- *Enhance public confidence by 1) increasing consistency and predictability in regulatory approach, while recognizing the need for flexibility among State and Federal regulatory programs, and 2) improving efficiency in implementing our regulatory oversight responsibilities.*
- *Improve the effectiveness and efficiency of regulatory programs nationwide by enhancing collaboration, through exchange of information and resources, promoting consensus among regulatory agencies and optimizing use of resources on a national level.*
- *Reduce unnecessary regulatory burden by promoting a consistent regulatory approach nationwide which will offer efficiencies for licensees and greater predictability for stakeholders.*

**NRC Stakeholders:**

- *Keeping NRC employees informed of current Working Group activities*
- *Enhance stakeholder understanding of the draft product being developed and the process used by the Working Group*
- *Minimize concerns regarding potential changes in their roles as a regulator and potential transition in organization or activities*
- *Seek and respond to comments and feedback of stakeholders*

**APPENDIX B****Communication Plan - cont'd****State Regulatory Stakeholders:**

- *Keeping State radiation control program staffs informed of current Working Group activities*
- *Enhance stakeholder understanding of the draft product being developed and the process used by the Working Group*
- *Minimize concerns regarding potential changes in their roles as a regulator and potential transition in organization or activities*
- *Seek and respond to comments and feedback of stakeholders*

**Other Regulatory Stakeholders (EPA, OSHA, DOT, FDA and others):**

- *Informing other potentially affected regulatory stakeholders of current Working Group activities*
- *Enhance stakeholder understanding of the draft product and its potential impact on any shared responsibilities or areas of interest*
- *Seek feedback on potential impacts on other regulated activities or relationships between regulatory agencies (State and Federal)*

**Industry and Licensee Stakeholders**

- *Keep regulated stakeholders informed of Working Group activities*
- *Enhance stakeholder understanding of potential impacts of the draft product on stakeholder licensed activities*
- *Seek input on areas where regulatory burden can be decreased and efficiency enhanced*
- *Seek feedback and respond to stakeholders*

**Public**

- *Inform public stakeholders of the issues and Working Group activities*
- *Seek feedback on whether proposed options meet strategic goals (e.g., maintain public health and safety, increase efficiency and effectiveness, etc.)*
- *Seek feedback and respond to stakeholders*

**APPENDIX B****Communication Plan - cont'd****Citizen and Environmental Groups**

- *Inform public stakeholders of the issues and Working Group activities*
- *Seek feedback on whether proposed options meet strategic goals (e.g., maintain public health and safety, increase efficiency and effectiveness, etc.)*
- *Seek feedback and respond to stakeholders*

**Working with Regulatory Stakeholders**

*The Working Group recognizes that options developed for the National Materials Program and adopted by the Commission may change relationships between the Regions, NMSS, OSTP and the States. Since these changes will affect how administrative and technical staffs for NRC and States perform their work, it is important that the Working Group provide these groups with information on the screening process and options and solicit their comments and input during the process of developing recommendations. Although dissemination of information will primarily be done using electronic and written communications, the Working Group considers it important to meet with stakeholders and make presentations at NRC and Agreement State offices and regional and national meetings to transmit key messages, provide updates on current activities and solicit input from staff, supervisors and management.*

*The Working Group plans to visit each of the NRC regional offices and headquarters during the development phase of the project and when the draft Commission Paper is prepared to make a presentation to NRC regulatory stakeholders to solicit their input. Outreach targeted at State regulatory stakeholders will include a poster presentation at the CRCPD annual meeting, a table top exercise at the annual OAS meeting, and a presentation and poster at the annual NERHC meeting. The Working Group has also scheduled its meetings at NRC and State offices to provide ready access for regulatory stakeholders.*

**Working with Non-Regulatory Stakeholders (licensees and public)**

*The Working Group recognizes that non-regulatory stakeholders' activities may also be impacted by options developed for the National Materials Program and adopted by the Commission. NRC and Agreement State licensees may be affected by changes in regulatory programs at the State and Federal level; therefore, it is important that licensees be made aware of the Working Group's efforts and provided opportunities to give their input during the development of options and recommendations. The Working Group is seeking opportunities to receive input from licensees, particularly regarding issues relating to improving efficiencies*

## APPENDIX B

### Communication Plan - cont'd

*and identifying areas where changes in the materials regulatory program could lead to reduction in regulatory burden while maintaining the current safety goals.*

*Consistent with the common goal of enhancing public confidence in our regulatory programs, the Working Group also recognizes that it is desirable to seek input from public stakeholders regarding any proposed changes to the materials regulatory program. Thus, the Working Group will examine methods by which we can actively engage public stakeholders by both providing information and seeking their input.*

*Although dissemination of information will primarily be done using electronic and written communications, the Working Group will seek opportunities to meet with non-regulatory stakeholders during the development phase of the project. This will include opening Working Group meetings to attendance by the public and presentations during industry and licensee workshops and meetings.*

#### Pilot Projects

*The Working Group plans to conduct a pilot project in conjunction with the annual OAS meeting. The pilot project will consist of an exercise involving representatives of the Agreement States and NRC in which the representatives will attempt to reach a consensus decision on regulatory priorities based on each agency's rulemaking and guidance development agendas. This pilot will provide the Working Group the opportunity to "field test" a key component of a national materials program. It will also provide the regulatory stakeholders the opportunity to compare individual agency agenda with their own and provide the Working Group feedback on the viability of sharing regulatory priorities and reaching a common agenda.*

*CRCPD G-34 Committee proposed a process for establishing a certification committee comprised of OAS, CRCPD and NRC members. The committee would act as certifying entity to review and approve certification regulations submitted by other agencies or groups.*

#### Electronic Communications

*The use of electronic communications is a key mechanism for providing stakeholders information and soliciting input and feedback from regulatory and non-regulatory stakeholders. The Working Group has established a web page, located with the OSTP web page, which is accessible to both regulatory and non-regulatory stakeholders. The web page*

**APPENDIX B****Communication Plan - cont'd**

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*includes the Group's charter, membership, screening criteria, evaluation of program elements, meeting summaries and schedule of meetings, among other products. The web page is maintained with up-to-date information and provides contact information to solicit feedback on the group's products. The Working Group plans to add links to other regulatory and non-regulatory stakeholder web pages.*

**Stakeholder Communication Issues**

*The Working Group has also utilized a joint State and NRC list server (Radrap) as a forum to communicate with regulatory stakeholders and plans to continue to use this resource to solicit input from regulatory stakeholders.*

**Written Communications**

*In addition to the web page, the Working Group plans to prepare articles for CRCPD and HPS newsletters which will include an overview of events and policies leading up to the creation of the Working Group and the development of options and the screening processes used. The articles will also provide information on how stakeholders can provide input to this project.*

**Meetings**

*All working meetings of the Working Group are open to the public and are posted on NRC's web page. A list of planned meetings and presentations are attached.*

**Interface with Commission Staff**

*In order to keep the Commission staff informed, the Working Group will invite the Commissioners' technical assistants to Working Group meetings held in NRC headquarters. The Working Group will brief the technical assistants on the current status of the Working Group's products and solicit their input.*

**Commission Briefing**

*The Commission will be briefed on the recommendations of the Working Group at the conclusion of the project, which is projected for May 2001.*

**APPENDIX B****Meetings and Outreach Activities of the Working Group**

March 6-8, 2000, Rockville, MD (NRC headquarters)	Working Group Meeting
April 10-12, 2000, Arlington, TX (NRC Region IV)	Working Group Meeting
May 15-17, 2000, Tampa, FL	CRCPD Annual Meeting Poster Session
June 5-7, 2000, Denver, CO (State of Colorado Offices)	Working Group Meeting
June 14, 2000, Rockville, MD	Steering Committee Briefing
July 25, 2000, Lisle, IL (NRC Region III)	Presentation to NRC Region III Staff
July 27, 2000, Rockville, MD	Presentation to NRC Standards Developing Organization
August 7, 2000, King of Prussia, PA (NRC Region I)	Presentation to NRC Region I Staff
August 21, 2000, Rockville, MD	Steering Committee Briefing
August 22-24, 2000, Rockville, MD	Working Group Meeting
August 24, 2000, Rockville, MD	Technical Assistants Briefing
September 6, 2000, Atlanta, GA (NRC Region II)	Presentation to NRC Region II Staff
September 11-13, 2000, Lisle, IL	Working Group Meeting
October 2-5, 2000, Charleston, SC	OAS Annual Meeting Presentation to States and Table Top Exercise Working Group Meeting
November 2000, HPS <i>Newsletter</i>	Articles on NMP and NMPWG seen by regulatory and non-regulatory stakeholders
November 2, 2000, Rockville, MD	Presentation to NRC Headquarters Staff
November 11, 2000, Austin, TX	South Texas Chapter Health Physics Society Presentation to Non-Regulatory Stakeholders
November 15, 2000, Mystic, CT	Annual NERHC Meeting Presentation to States and Regional Federal Staff
November 2000, Arlington, TX	Presentation to NRC Staff

**APPENDIX B****Meetings and Outreach Activities of the Working Group - cont'd**


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December 5-7, 2000, Rockville, MD	Steering Committee Briefing Working Group Meeting
December 2000/January 2001, NMSS <i>Newsletter</i>	Articles on NMPWG
February 20-23, 2001, Arlington, TX	Working Group Meeting
February 21-22, 2001, Arlington, TX	Public Meeting (transcript available at OSTP website)
January 2001, Atlanta, GA	Atlanta Chapter Health Physics Society Presentation to Non-Regulatory Stakeholders
March 20-22, 2001, Rockville, MD	Steering Committee Briefing Working Group Meeting
March 22, 2001, Princeton, NJ	New Jersey Chapter Health Physics Society Presentation to Non-Regulatory Stakeholders
April 3-5, 2001, Atlanta, GA (State of Georgia Offices)	Working Group Meeting
April 29-May 2, 2001, Anchorage, AK	Annual CRCPD Meeting Presentation to States

## APPENDIX B

## Questions and Comments from NRC Staff

The following questions were asked by NRC Staff during outreach presentations on the activities and status of the National Materials Program Working Group (NMPWG) from July through November 2000. Since the NMPWG continued to develop a National Materials Program (NMP) as it interacts with the NRC staff, the questions and comments raised were invaluable to the NMPWG in refining the NMP and clearly communicating the NMP at later meetings with stakeholders. The questions are grouped into four categories: historical, process, structure, and implementation.

### Historical

- *Has there ever been an example of a major rule making initiated by the States or the CRCPD?*
- *Have other federal entities or agencies pursued the NMP concept with the states?*

### Process

- *Why are all State National Materials Program Working Group (NMPWG) members from Agreement States?*
- *Who initiated the NMP effort? How will the NMPWG findings be presented to the Commission?*
- *What will the NMPWG use as evaluation criteria for options?*
- *Has the OAS or CRCPD expressed support and need for an NMP?*
- *Who in NRC promoted the SECY paper to initiate the NMPWG?*
- *Does senior NRC management support the NMPWG process?*
- *Is there some way to involve more non-Agreement States in the NMPWG process?*
- *Is there an expectation that the NMPWG propose options to the Commission and give recommendations?*
- *The WG should meet with large non-Agreement states and provide a presentation on what the NMPWG is doing and trying to accomplish (i.e., same outreach the WG is doing with NRC staff).*
- *The NMPWG should return to the Regions when the draft paper is completed.*

### Structure

- *What is the Conference of Radiation Control Program Directors (CRCPD) and Organization of Agreement States (OAS)?*
- *What are Centers of Excellence/Expertise?*
- *How are State radiation programs funded?*
- *What is meant by an NMP?*
- *The NMPWG needs to consider plural statutes (i.e., those statutes with overlapping interests) when looking at changing the Act.*
- *Will the NMP be an advisory committee or will it bring forth the things that NRC's Office of Nuclear Materials Safety and Safeguards (NMSS) does now?*

## APPENDIX B

## Questions and Comments from NRC Staff - cont'd

- *Can you give us any insight into what the NMP will look like?*
- *Doesn't the NRC write regulations because they are needed?*
- *The NMPWG should be aware that some states have no infrastructure to participate in an NMP.*
- *Has the NMPWG considered outside sources such as the National Academy of Science (NAS) report on medical regulation by the NRC?*
- *What is compatibility and how is it determined?*

### Implementation

- *Have all Agreement States brought into the NMPWG process?*
- *If States don't participate in the National Materials Program (NMP), will they still get the benefits?*
- *Why not use a "Work Control Center" to distribute NMP work?*
- *How will the NMP be funded?*
- *If Centers of Excellence/Expertise are used to share resources, how does one address consistency if the compatibility requirements allow States to be more restrictive with some NRC requirements?*
- *Has the NMPWG considered enforcement in the NMP, particularly the need for consistent application of enforcement across jurisdictions and sharing of information?*
- *How would the NMP handle a situation that occurred several years ago when some states explored regulating Veterans Administration (VA) hospitals and the VA shot down the idea in a hurry?*
- *Can the states tell the NRC that a regulation is needed?*
- *How would the NMP handle a recent situation where the NRC went to the States to get consensus on writing a radiography certification exam in Spanish? Although there was compromise reached that was not adequate, consensus did not work on this simple problem. The entire episode was embarrassing and complicated by some states having English only laws.*
- *The NMPWG needs to consider how the NMP will affect the U.S. Territories (Puerto Rico, Guam, etc.).*
- *The NMPWG needs to consider the impact of States entering Indian Tribal lands.*
- *Has the NMPWG considered specific changes needed to the Act?*
- *How long will it take to change the Atomic Energy Act?*
- *If NRC activities are restructured, how will that apply to States and other federal agencies?*
- *The NMP must track and follow centers of excellence/expertise. These centers must be identified rapidly and effectively response to changes in these centers.*
- *How will the NMP identify centers of excellence/expertise? Will the NMPWG come up with the criteria?*
- *Does geography have to be a constraint to identifying centers of excellence/expertise? Can there be multiple centers of excellence/expertise for the same element?*

## APPENDIX B

## Responses to Stakeholder Questions at NERHC Meeting

Responses to Questions Distributed to Participants Meeting November 15, 2000

What problems have you encountered with interactions with government agencies (State/Federal)?  
How could it be fixed?

Lack of uniformity with standards, philosophy, approach to radiation regulatory matters in all Federal agencies. I submit there may be more variation here than between the individual states in many areas.

Interagency federal bickering. The fix, have one agency set limits

Communication between the NRC and States, i.e., notification of NRC inspection in an Agreement State only after the NRC conducts inspection (no chance for accompaniment) and inconsistent site release standards between federal agencies - States are coming up with their own.

Are there any other programs (regulatory or other) that could be used as a model for the National Materials Program (NMP)?

Have seen great things develop under the NRC/Agreement State program. The present IMPEP situation is very good. I have noticed recently however that the states seem to have much less respect or consideration from the NRC Commissioners. Maybe one of the NRC Commissioners should be the CRCPD Chairperson or a CRCPD elected official.

How could consistency between regulatory programs be improved?

Start at the federal levels, more resources

You need buy-in of the States. This may be increased with more tie-ins to the CRCPD or OAS. The reason I emphasize the CRCPD is because of the suggested state regulations and the breadth of the working groups.

Have only one set of regulations - this set of regulations should be agreed upon by all parties involved.

How do you feel about NRC concurring with States on regulatory priorities?

Uncomfortable if the NRC is the controlling agency with the States as second class partners. Will we develop a relationship similar to Federal government and Indian Nations? States provide funding with major NRC control?

Constitutional issues here.

I believe that some States do have better ideas when it comes to regulation and enforcement. I think that IMPEP can adequately identify these areas.

This is very important, especially with nuclear power plant decommissioning.

## APPENDIX B

## Responses to Stakeholder Questions at NERHC Meeting - cont'd

Does NRC need a "lead" function?

Too broad an interpretation for an intelligent response

Certainly NRC has a national interest and congressional requirements. There should be a lead function but the states need more input. In a democratic society, maybe the states need as much pull in materials issues as we also issue machine licenses and material licenses.

Yes

Are there additional responsibilities that States should assume?

Not known

I believe that states already assume all the required responsibilities. We know, however, that some of the CRCPD work done on say, SSRCP Part D, that is not as important as the NRC's Part 20 work being done and thus gets put on the back burner. Maybe we need to integrate the process by elevating the CRCPD process and get better buy-in to the NRC process.

What problems do regulatory agencies have working with each other?

Turf battles, perverse human nature

Lack of definitive direction from above. The agency heads act in a nearly autonomous manner. We understand that the NRC and EPA need to work together on limits for example. The fact that they haven't and that it will only be solved by congressional action eliminates science from the process and is directly the responsibility of the agency heads - a national disservice.

How can information sharing among agencies be improved?

Continue with the quasi-neutral ground the CRCPD provides.

Regular meetings together at a range of different levels.

E-mail and web site - RadRap is a great tool now.

How would you identify a Center of Expertise?

I do not see this as a major issue. Expertise is usually apparent. Perhaps the issue may be to accept the apparent.

Rough identification could be based on experience and time. The Texas industrial radiography test is an example. They have the most people with the longest experience.

Looking at how much work they have done and how long on a particular issue -, i.e., PET licensing and inspection.

## APPENDIX B

## Responses to Stakeholder Questions at NERHC Meeting - cont'd

What are the alternatives to the current system of compatibility designation?

Abolish the concept of "Agreement States" as now seen, as having served its purpose. Control over weapons, source material and such could be returned by the Federal government.

The compatibility designation I think can work very well. The application of the designation and the assignment of the designation are the areas of disagreement. The problem is the subjectivity in the process.

Do you know of any statutes that would impact the Alliance?

I am sure there are many. Start with the point that an individual state is the final authority regarding the health, safety, and welfare of its citizen.

I am unclear on the Alliance and don't feel I can answer this question yet.

Should the Alliance be a regulatory function? Or should the role be extended to "outreach" (i.e., funding a study, etc.)?

At present, with the current climate, developing a regulatory operation will see their results crammed with fish hooks.

If the state were to specifically be included in the process then I expect it would need to be included in the NRC regulations and statutes so as not to be at the whim of the OED and the Commission. But the Alliance shouldn't need to have a regulatory part - Just tie all the available staff together.

If we can't implement the complete Alliance concept as envisioned, what are the minimum changes that you would want?

Abolish the concept of "Agreement States" as now seen, as having served its purpose. Control over weapons, source material as such could be returned by the Federal government.

CRCPD on the NRC Commission.

Regulatory

What role should Non-Agreement States have in the Alliance?

A key question: We see little in this effort that serves non-Agreement States.

I believe that no one should be specifically excluded. I think that they should not hold office or official positions, but they should not be left out. They can still have good ideas.

**APPENDIX B****Responses to Stakeholder Questions at NERHC  
Meeting - cont'd**

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**What role should industry/professional groups have in the Alliance?**

**Same as any other regulatory process. The regulated community, out of necessity, must be fully involved. U.S. philosophy, in part, is consent of the governed to be governed.**

**As the Alliance sees fit. We may need professional help!**

**Their voice should be heard and implement changes they recommend.**

**How can the Working Group best exchange information with State staffs?**

**Through CRCPD.**

**RadRap works well in our State - additional information can be transmitted through CRCPD e-mail.**

**Additional comments and suggestions**

**Just seems on the surface to further the agreement process with incentives to become an Agreement State. Further, assumes radionuclides are the radiation control issue. I submit that machines are an important component, probably larger. Where are they? Radon? This appears to be money driven in part with the advent to non-Agreement States. Perhaps the "Agreement State" concept approaches moribundity.**

**APPENDIX B****Input from Health Physics Society Focus Groups**

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South Texas Chapter of the Health Physics Society  
November 11, 2000

What types of issues/problems have you had interacting with government agencies (state or federal)?

A key element that needs to be considered with this effort is a continual reassessment of existing rules, answering the question "do they add any value to the public health?" Ex. Common violation in Texas has to do with package receipt and survey of packages, yet the fact is that packages don't leak, especially single use packages. Maybe the levels could be change in rule. Consider not adding additional layers of bureaucracy, but look at taking out layers that aren't adding to public health.

This Alliance should be considering compliance associated with license conditions imposed in lieu of rulemaking. This is considered unconstitutional by circumventing rulemaking process so the violations don't hold water. Consider a "parking ticket" for that instead of a notice of violation (NOV) process. Licensees are judged by NOV's received because there are no dead bodies in this industry.

We respond to proposed rules based on workload. Using consensus standards has merit. For instance, the Health Physics Society (HPS) guidance on decommissioning compared to MARSSIM, which is gross and unusable...uranium orders of magnitude more restrictive than MARSSIM. Rely more on industry than on internal government promulgation (rulemaking/guidance).

Compatibility rules come with assumption that rule is going to improve public health and I would argue that point. Is it truly improving public health? Look at any regulatory action to see if really necessary first, regardless of what type of structure implements it.

What has changed with the increased volumes of rules, with exception of radiographers, that has actually done something to improve radiation safety? I would argue that the vast majority of rules have done nothing to directly to improve public health. Go towards performance-based rules, i.e., do you have a program to ensure such and such and are you following it, rather than writing detailed rules. Define the desired outcome rather than the how of getting there and spend time inspecting to ensure licensees are following their safety programs.

Approach should be performance-based using consensus standards...don't need to reinvent wheels. As long as the outcome is accomplished, fine.

## APPENDIX B

## Input from Health Physics Society Focus Groups - cont'd

**Should a National Materials Program include all types of radiations?**

Yes... a licensee finds itself trying to develop policies for their facility and explaining them to several different agencies. It's also hard to explain to users why three different sets of rules apply to radioactive materials. For instance, NESHAPS were written with power plants in mind and those assumptions don't always fit hospitals, academic institutions. It is impossible to manage rules like that.

A VA hospital is an NRC licensee in Texas with x-ray machines and other than byproduct...the NRC jurisdiction very incomplete...if we have problem with something other than byproduct, they throw their hands up and walk away because they don't have jurisdiction. What role has the NRC agreed to play in this (Alliance)? Since AEA limits their role, if they decide not to participate, can they just walk away and do what they do now?

The NRC should get out of the medical side altogether because their oversight's not complete.

I worked at a research reactor and it was NRC inside reactor and TX outside. This creates a lot of unnecessary paperwork which would certainly be eased with one set of regulators.

**What do you see as your role in the Alliance (as a professional society and as a licensee)?**

How much do professional society's have a role in this? Like HPS, what is their input and what has their involvement been so far?

**Does one entity need to have a lead function in the Alliance?**

In TX, we went from BRC handling all waste issues to having it split out into several state agencies and then coming back together, but its still not under one roof. How many other states are in the same boat? Do you have everybody at the table to address these kinds of issues across all RAM issues (like Texas Railroad Commission and Texas Natural Resources Conservation Commission) ...rather than forming a fiefdom system where someone can say, wait a minute I'm not playing that game because you didn't ask my opinion, so I'm not letting the rad waste folks into the new world order.

I think there should be one lead agency/group and it should be responsible for setting goals and holding the other agencies/groups accountable. This would help lead to consistent regulation and hopefully interpretation. Should it be NRC? I don't think it would have to be. CRCPD or OAS would be possible...or maybe all three together. I believe this would keep everyone focused. I have some concerns that it will be difficult to get everyone (NRC, Agreement states, EPA, waste agencies, etc.) together and work as a consensus group...too many conflicting agendas and it might be difficult to develop a usable product for licensees.

## APPENDIX B

## Input from Health Physics Society Focus Groups - cont'd

How is a National Materials Program going to be evaluated/assessed?

The challenge you face in getting this group together is how a bunch of regulators are going to identify what a good program is. Each has its own biases towards being regulators and what a good program is. I think it would be nice to have an objective measure of that. The only indication that regulators have is that our rules are a little thicker...how many violations we issue...but evaluation is all within regulatory community. You have to get an objective measure outside of that....something outside of IMPEP. Maybe dosimetry data?...doses per workers in Texas vs. others. Otherwise, an evaluation would be like a bunch of car dealers assessing what's a good car without knowing what the customer wants.

How are you going to know if this works? How are you going to know if the Alliance is a success or failure? What will it be measured against?

Are there other organizations, etc. that could be evaluated as model for a National Materials Program?

I can't think of another health-related entity that gets outside objective evaluation to be able to quantify it to management and other outside stakeholders, but this is an opportunity to take a professional leadership role and say we're going about things that are prudent. It's pretty tough to compare the radiation gig to tangibles in other programs such as vaccinations, heart disease. I don't think regulatory agencies across the country fully appreciate the pressures practicing professionals are under because we can't produce a body count...all that can be produced are violations, license fees, etc. So upper management tends to view it as a paper tiger. Think about objective measures.

ISO 1400 standards might be considered as a model because they are performance-based, not prescriptive. You read two pages before you get to the first "thou shall" and only on last page was the word "record."

Try looking at FFA. They regulate from the manufacturer to operation, but I'm not sure if they're as performance-based as needed.

Make every state an agreement state and leave NRC with reactors.

What are the positive things/negative things you see with the Alliance?

We tend to respond to proposed rules based on our workload. Using consensus standards is a good idea. For instance, the HPS guidance on decommissioning is much better than MARSSIM which is gross and unusable. You should rely more on industry standards than on internal government workings (government development of rulemaking/guidance).

Approach should be performance-based using consensus standards. You don't need to reinvent wheels. As long as the desired outcome is accomplished, fine.

## APPENDIX B

**Input from Health Physics Society Focus Groups -  
cont'd**

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I would hate to see us lose, as a consequence of "nationalizing," some of the latitudes that states have that allow us to operate in a more reasonable fashion. For instance, Texas' 300-day half-life rule is risk-based, safe, and provides cost savings. If a national structure can allow that latitude for positive and pragmatic rules/ guidance, that's a good thing.

If this group could come up with consistent set of rules that apply to all radiation and can do it as briefly as possible that would give us the flexibility to develop our own programs. It would be a tremendous help and allow use of consensus standards. You could shorten the rules by consolidating regulation of different uses into one set of rules, which would allow one inspector from one agency to inspect all radiation use at a facility. This not only saves time, but also gives us better feeling. However, if consensus means putting everyone's opinion down, you will end up with documents that are thicker than what we have now. Beware of building consensus by adopting everyone's *opinions*.

Is public safety any better because we have to jump through all the hoops now required under expanded rules for license applications, operation, etc.? Our program is basically the same thing. The rules are so prescriptive that they have removed the flexibility of the RSO at a facility to come up with a program to achieve an outcome. The only way to get consensus is to have more performance-based rules rather than very detailed rules.

I am often frustrated by differences in knowledge of regulators on certain topics. No one regulator can be knowledgeable on every single topic. If I have ten radiation "topics" in my facility, I'm very knowledgeable about those and I've hit regulator that's not...I get frustrated. By using centers of expertise, our jobs would be easier because we would be communicating on same plane and we wouldn't have to explain or teach along the way. Using centers of excellence might make the process easier. It would be unreasonable to believe that any one licensee could be expert in all health physics areas, so its also unreasonable to believe that regulators should be expert in all fields.

Would the Alliance have any implications for getting individual states to get their waste disposal acts together?

Waste is a system that's broken. NRC separated the issue of power plant waste vs. everyone else's waste so the power plants have more of a solution, but we in the states can't separate the two. NRC is doing things for power plants...entombment, rubbleization...but these give no relief to waste problems other entities face. We need to bring those back together.

In the Alliance, we could have more of opportunity to input (just like we're doing here). What we would like to see in rulemaking is to get consensus from licensees and more consistency in rules...a uniform set of rules.

What's working with the system now? Dose limits/standards. The rules should just set out standards and don't prescribe how to meet those. Be consistent with standards and use compliance with those standards as an objective measure.

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

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**Who are the stakeholders and what kind of input has the working group received from stakeholders?**

**Other stakeholders? Possibly IAEA...consider international agencies in terms of the structure and allowing input from those global entities.**

**Who is the public..who are you going to approach? The Texas Radiation Advisory Board has general public members...you could invite input from folks like that.**

**There are a lot of people that are industrial hygienists that are assigned the role of RSO. They have an interest, but don't tend to get involved in groups like HPS because they don't particularly associate themselves as health physicists. Consider other safety professionals that may be in the RSO role. Use list of RSO's that you (Texas BRC) have.**

**Has any of the work or input been put on the web site to solicit information/input?**

**Put a link to the NMP web site at BRC web site and at the STCHPS web site.**

## APPENDIX B

## Input from Health Physics Society Focus Groups - cont'd

Atlanta Chapter of the Health Physics Society  
January 2001

What types of issues/problems have you had interacting with government agencies (state or federal)?

The biggest obstacle I can see is where different agencies (federal/state/local) have conflicting regulations. Normally, the most restrictive is applied, but it would be nice to have one set of rules to follow.

One set of rules & regulations for all states to follow, updated and put into action all at the same time. I think NRC should do this.

Occasional problem of getting a definite answer within a week's time. Often a problem getting copies of government publications that are cited by Agencies, but are no longer in print or on the Internet.

Having worked on both sides, I can appreciate the blinders that can develop in one particular position (job). Effort needs to be constantly placed on looking at the other guy's position/purpose. A balance needs to be struck between the 'law' and true safety and effectiveness, not just meeting the letter of the law. I have, in the past, had difficulty getting access to not only the regulations, but supporting guides and policies.

Staff may not be empowered to work with staff of other groups, leaving intergroup communications to top management rather than to intergroup teams who could be more productive.

Should a National Materials Program include all types of radiations?

A National Materials Program should include all types of radiation, including natural. All radiation should be treated the same in the regulations, regardless of its origin.

No (maybe microwave & laser) really not sure where other radiations should be.

No. I have a concern of everything being micro-managed, over-regulated out of all proportion to actual risk levels and harm, as the NRC has done with nuclear medicine. The burdens of paperwork (etc.) in cost, time and manpower have always been grossly underestimated by the government.

I tend to be slow to warm up to change and will have to be convinced that the benefit of including all radiations will result in either more efficient programs or safety and less needless 'paperwork'.

Yes. Medical x-ray and radioactive material should be included under same regulatory umbrella for consistent national protection of the population. A child would not know less harm if their radiation dose was delivered by an unnecessary computerized tomography operation or an unnecessary x-ray than an inadequately shielded radioactive source.

## APPENDIX B

**Input from Health Physics Society Focus Groups -  
cont'd**

**What do you see as your role in the Alliance (as a professional society and as a licensee)?**

To show government how radioactivity is used in the 'real world'; how it should be realistically managed to achieve the user's purposes without undue risk to the public. The government should be made aware of the results of studies showing radioactivity's effects on the human body (much less than ever estimated). We should keep government updated on results/benefits achieved from our work with radioactivity.

As a consultant, I will need to try to keep the lines of communication open both ways – to the regulators and to the clients.

Providing advice, guidance, and volunteer time to support radiation safety activities

**Does one entity need to have a lead function in the Alliance?**

There should be a lead entity in order to resolve potential disputes. The national body (NRC) is the natural choice to lead such an Alliance.

Yes (NRC)

There are both advantages to having one lead but there are also disadvantages. I think that the radiation field is so diverse that it will be a major adjustment to put all in one basket. The corporate history at most institutions will fight the change to a one-agency program. Just look a how long it is taking to change over to metric from the OLD ENGLISH.

Yes. Without a lead activity, the program will lack focus. The lead activity should receive Congressional funding for this effort. Perhaps Congress should provide incentives for all states to come under the same regulatory net.

**How is a National Materials Program going to be evaluated/assessed?**

By the NRC (we still need a strong central group)

The NMP will have to be evaluated in a manner to allow three things to still work: (1) Separation of State and Federal; (2) Programs and policies that are based on function not just resources and simple plans to reorganize; (3) Clear and reasonable objectives need to be established and delineated before sweeping changes are put into place.

Under revised NRC regulations under which the Agreement States would function. This would likely require a re-enactment of the Atomic Energy Act under another name (Radiation Oversight Act) to pull in NORM and TENORM.

**APPENDIX B****Input from Health Physics Society Focus Groups -  
cont'd**

**Are there other organizations, etc. that could be evaluated as model for a National Materials Program?**

No (need only one, NRC)

I have limited knowledge of materials programs but, the MQSA/FDA fee for service-contracted-to-states has potential. Major harmonization with Fed law and the ability of states to modify their laws need to be included in the process.

As a concept model, CDC has centers for specific tasks, such as National Center for Environmental Health, National Center for Infectious Diseases, etc. Centers for licensee support could be established (perhaps by a bid process) in various states, such as a National Center for Radiography located in Texas or Louisiana where radiography companies are quite active. Others could include the Center for Medical Therapy, Center for X-Rays, Center for Calibration, Center for Licensing, Center for Operational Oversight, etc. Those centers could specialize in supporting one type or group of licensees, and inter-center functional interfaces would be beneficial. - Amend the Atomic Energy Act to give the licensee overseer authorization to control, manage, license, and audit x-rays, accelerator-produced RAM, NORM, TENORM, etc. - Then change the title of Nuclear Regulatory Commission to break the past mold and lead into a new future. An example is the Radiation Safety Agency, with subgroups called the Centers for Radiation Safety. The emphasis is that radiation can and will be used safely and consistently. - Lean toward using general funds rather than licensee fees, or a combination to ease pressure from both sides.

**What are the positive things/negative things you see with the Alliance?**

The Alliance's greatest benefit is probably as an information-sharing group. States and NRC should share their analyses and data so that others do not have to reexamine the same problems or issues.

Maybe hard to get agreement if too many folks get involved. Some group needs to step in and say: 'this is the way it is going to be' & all licensees, states, etc., follow the same book of rules at the same time.

See all the above

Positive: More consistent and manageable set of regulations, more uniform protection of all facets of the public (child health, under represented populations, sensitive populations), reduction or elimination of duplicate effort by multiple regulators with different focuses (reduced size of government), lower cost of regulation. -Negative: Overcoming the rice bowl effect may be emotional, change may initially be painful.

## APPENDIX B

## Input from Health Physics Society Focus Groups - cont'd

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New Jersey Chapter Health Physics Society  
March 22, 2001

What types of issues/problems have you had interacting with government agencies (state or federal)?

Different sets of regulations and standards  
 NRC - very professional; New York State - somewhat political, not professional and misinterprets its own regulations  
 None (2 times)  
 Poorly worded regulations; difficult to follow, need to get interpretation from regulatory agency  
 Inconsistent requirements (e.g., decontamination and decommissioning total effective dose equivalent of 25 mrem/yr for NRC, 15 mrem/yr for New Jersey). Redundant regulations or obsolete regulations that are not updated  
 Both - technical knowledge isn't as well as I would like  
 None on routine basis. Lack of consistency from inspector to inspector when they come on site.  
 Can be inflexible, especially with new or unique situations. Several times I've been told the regulation was not written for that situation, but try to comply anyway.

Should a National Materials Program include all types of radiations?

Yes (3 times)  
 Yes, because New Jersey is implementing draconian dose limits for NORM in soil (e.g. 3 mrem/yr)  
 Yes, otherwise, there will always be regulatory agencies against the Alliance (e.g., DOE)  
 Yes. One consistent voice is the best way to go. Multiple agencies and federal and state involvement is too complicated (just look at asbestos regulations)  
 No. Neutron sources should be regulated by a single agency. Much more dangerous than the three other types  
 Should include NORM, accelerator and reactor. Not x-ray, microwave, NMR  
 Yes, it would make it easier for a safety department  
 All ionizing radiation sources that are not natural

## APPENDIX B

## Input from Health Physics Society Focus Groups - cont'd

**How is a National Materials Program going to be evaluated/assessed?**

How realistic and practical the ultimate program is; Will it have money; How it encourages or discourages commerce

Take evaluations from each license holder

Will it improve on the current way of doing business

Performance indicators

Did anything bad happen? Is everything accounted for?

Force States into uniform response to licensees. Between states, NY State Department of Labor does not issue license or regulations to licensees, Massachusetts requires HP consultants to register. Use federal money to research and publish new regulations consensus

Unfortunately, money will be a primary factor

Performance based - are there problems out there and are they being addressed properly?

**How could consistency between regulatory program be improved.**

It would be nice to have overall consistency

A council that involves each state regulation makers might be able to help in consistency Keep basics uniform across the country. Hard to be consistent with everything in each state. Agreement on this would be hard to achieve

Have one set of standards for all as viable and feasible. Avoid multiple inspections by different regulatory agencies

If I had a good answer to this question, I'd be rich (or at least a decent politician)

Ensure good science goes into regulations. Force a state to perform a justification of regulations on doses that are more stringent than NRC regulations - must include risk based assessment.

Use a consensus committee

Base concentration limits on dose - period! One agency could control all exposure to radiation doses.

Design a single agency for radiation; state or federal or clear demarcations, i.e., all air emissions are EPA, occupational exposure NRC, all medical programs by the states

**Are there other organizations, etc. that could be evaluated as model for a National Materials Program?**

State EPA agencies

Perhaps organizations outside the United States

Development of MARSSIM manual

## APPENDIX B

**Input from Health Physics Society Focus Groups -  
cont'd**

**What do you see as your role in the Alliance (as a professional society and as licensee)?**

- To give feedback as far as how well they are doing and what changes are needed
- Provide comments/insights to be used in formation of policies and regulations
- Not as a licensee, but a society should have a voice in rule making through commentary and input
- The Health Physics Society should be separate equal member in the alliance. Separate from State and NRC and corporations/business. Licensees (as businesses) already have a voice through the political entities that would be in the alliance
- Open minded to listen to issues from another member's viewpoint
- As a licensee, one set of regulations, especially when one has facilities in a number of states
- Victim, vocal participant

**Does one entity need to have a lead function in the Alliance?**

- Yes (2 times)
- Depends on what and extent of lead function means
- The Alliance should have a Commission representing its constituency
- Yes, federal NRC to ensure overall consistency and a steady driver
- Yes, it is all well to have it as a committee decision, but there needs to be one leader
- Yes, probably at the federal level

**What are the positive things/negative things you see with the Alliance?**

- Greater freedom for each State is a positive, difficulty with compatibility is a negative
- Will be hard to get consensus
- Positive: standardization of statutes, optimal use of resources; Negative: possible lack of adequate representation for Non-Agreement States
- Positive: stop redundancy, move NRC from parent to adult role in dealing with licensees.
- Negative: a consensus decision is hard to come by (no quick decision), will probably cost more on administrative costs, loss of good science to balance view
- Some states will resist any change
- I need to hear more about it

## **C. Evaluation of Program Elements**

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- **Summary of Program Element Evaluations**
- **Materials Licensing Guidance**
- **Materials Inspection Guidance**
- **Materials Licensing and Inspection**
- **Performing Materials Inspection**
- **Performing Materials Licensing**
- **Reciprocity**
- **Technical Guidance Documents**
- **Training, Qualification and Experience Standards**
- **Regulatory Program Reviews**
- **Regulatory Program for General Licensees - Regulating Agency**
- **Regulatory Program for General Licensees - Implementation**
- **Certification Program**
- **Rulemaking**
- **Information Infrastructure**

## APPENDIX C

### Summary of Program Element Evaluations

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The Working Group identified and evaluated potential program elements required to support a "National Materials Program" as part of its initial evaluation process. Candidates for the group of program elements were selected by the Working Group based on current program elements common to NRC and Agreement State regulatory programs. The group used IMPEP and CRCPD guidance as a basis for identifying program elements. The following program elements were evaluated:

- **Materials licensing, with particular focus on guidance governing the licensing process;**
- **Materials inspection, with particular focus on guidance governing the inspection process;**
- **Alternative options for States to perform licensing and inspection functions for all facilities within their respective State;**
- **Implementation of the materials inspection program;**
- **Implementation of the materials licensing program;**
- **Reciprocity, or the States' and NRC's process for allowing a materials licensee to conduct licensed operations in areas under another regulatory agency's jurisdiction;**
- **Technical Guidance, with specific focus on procedural guidance for specific activities that may be used by licensees in support of their programs or license application submittals;**
- **Training, Qualification and Experience Standards for regulatory personnel;**
- **Regulatory program reviews;**
- **Regulatory program for general licensees;**
- **Certification Programs;**
- **Rulemaking;**
- **Information Infrastructure;**
- **Incident/Event Response and Coordination;**
- **Generic Event Assessment; and**
- **Research (anticipatory and confirmatory)**

It should be noted that the program elements were intended to be sufficiently broad to capture a full spectrum of activities. For instance, material licensing is intended to include licensing source, byproduct, and special nuclear material. Thus, these elements include consideration of specific byproduct materials licensees, uranium recovery facilities, and sealed source and device reviews, among other types of licensing activities.

## APPENDIX C

### Summary of Program Element Evaluations - cont'd

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#### Summary of Recommended Alternatives for Program Elements

##### *Materials Licensing Guidance*

NRC/Agreement States (AS) should jointly develop an agenda and priorities for developing licensing guidance. NRC/AS either use working groups to develop guidance or direct other organizations/entities to develop guidance when appropriate.

##### *Materials Inspection Guidance*

NRC/AS should jointly establish priorities and develop inspection guidance. Joint working groups should be used to develop guidance. Alternatively, NRC/AS may also accept consensus standards (following review and revision, if needed) or contract with other organizations to develop guidance when not available and needed.

##### *Materials Licensing and Inspection - Alternative for States to Perform Licensing and Inspection for All Facilities within Their Respective State*

The Working Group requires input from OGC regarding legal issues that may be associated with AS either being granted statutory authority or delegated authority to perform licensing, inspection and enforcement for Federal and other facilities normally regulated by NRC.

##### *Performing Materials Inspections*

Maintain the current inspection program, but supplement the existing program with other options. NRC would perform inspections for all facilities authorized to possess/use AEA materials in non-AS and at federal facilities in AS. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS would inspect facilities located in their respective states. Supplemental options would include: 1) allowing other entities to contract with NRC/AS to perform inspections and report results to the appropriate regulatory agency; 2) allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC/AS or reduce inspection effort by NRC/AS; 3) accept audits performed by other organizations and use these as a supplement to NRC/AS inspections to reduce inspection effort by NRC/AS; and 4) use "Centers of Excellence" to perform inspections of specific technical areas. Acceptance of licensee audits or audits performed by independent organizations to modify NRC/AS inspection effort would be determined by the appropriate regulatory agency in a selective manner. "Centers of Excellence" could be either AS or NRC organizations and would be jointly recognized by AS/NRC.

**APPENDIX C****Summary of Program Element Evaluations - cont'd*****Performing Materials Licensing***

Maintain the current program and enhance both NRC and AS reviews through use of contracted entities or "Centers of Excellence" to perform some license reviews or portions of reviews for specific technical areas.

***Reciprocity***

The Working Group solicited comments from State stakeholders on this issue since NRC is the only regulatory agency that enters another agency's domain to conduct inspections of licensees working under reciprocity. (Note: AS cannot enter another State to conduct inspections of AS or NRC licensees working within their State.) Based on comments received, the Working Group determined that a recommendation for change in this area was not warranted at this time. The Working Group's conclusion would not preclude examination of this process under a separate initiative.

***Technical Guidance Documents***

Some organization would maintain a clearinghouse of technical documents evaluated and approved by the National Materials Program for use. Consensus on priorities, needs and recommendations for organizations to develop guidance should be jointly established by NRC/AS.

***Training, Qualifications & Experience Standards for Regulatory Personnel***

Maintain the current program and enhance with: 1) use of a clearinghouse of training ideas, resources and opportunities designed for or employed by NRC/AS; 2) allowing licensees to provide training, on a voluntary basis, for specific technical issues or consider contracting with licensees to train staff in specific technical areas; and 3) encourage a regulatory agency exchange program to develop staff in specific technical areas.

***Regulatory Program Reviews***

Utilize team (NRC/AS) effort in conducting program reviews using IMPEP guidance, but fully implement use of "Centers of Excellence" to assist with team composition.

***Regulatory Authority for General Licensees - Regulatory Agency***

This needs to be examined concurrently with the following element. The Working Group recommends that this be discussed with the Steering Committee for consideration of whether a second working group should evaluate the General License program.

## APPENDIX C

# Summary of Program Element Evaluations - cont'd

### *Regulatory Program for General Licensees - Implementation*

Some of the options were rated by the Working Group; however, given the discrepancies in how these items are regulated and the number of questions regarding the basis for authorizing distribution and use of generally licensed items, the Working Group elected to discuss this element with the Steering Committee. The Working Group is seeking advice on whether this issue should be reviewed by a separate group.

### *Certification Programs*

Use CRCPD's G-34 Committee Certifying Entity process as an example (with minor modification) of how an element of a National Materials Program could work. Evaluate successes and problems identified by G-34 during initial implementation of the process, and document input received from G-34 with the working group's report.

### *Rulemaking*

NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using "Centers of Excellence" where possible.

### *Incident/Event Response*

Maintain certain aspects of the current system, i.e., use of a centralized public event reporting system, consolidated reports to Congress and coordination of contacts between Federal and State agencies, with enhancements. Enhancements would include joint development of guidance and procedures for posting event reports to public information systems and AS assuming greater responsibility for entering event data in public systems. Continued coordination of event response between NRC and AS when necessary would facilitate prompt notification of all affected parties for events which cross jurisdictional boundaries or involve generic safety concerns. AS would also assume greater responsibility for preparing input for the annual Abnormal Occurrence report.

### *Generic Assessment for Events*

Maintain some elements of the current program with enhancements, including: 1) have AS assume greater responsibility for generic assessment and for drafting proposed actions; 2) have AS assume a more active role in making decisions on appropriate responses to significant generic issues; and 3) seek broader input in decision making for long-term actions. Elements of the existing program that would be retained include NRC internal use of a Generic Assessment Panel (GAP) process and centralized review of proposed actions for both short- and long-term. This contributes to consistency in regulatory approach over a period of time and allows all parties an opportunity to participate in decision making.

## APPENDIX C

**Summary of Program Elements Evaluations - cont'd**

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***Materials Research***

AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding and resource expenditures could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

**APPENDIX C****Summary of Program Element Evaluations - cont'd****Process for Evaluation of Program Elements**

The process used by the Working Group included identification of existing processes or methods for accomplishing program goals within State and NRC regulatory programs, as well as other options for each program element. Additional options evaluated by the Working Group included, in some instances, elimination of the program element as well as alternatives for accomplishing the specified outcome. Each option, including the existing mechanisms, was evaluated against criteria defined in the Working Group's Mission Statement. These included:

- A. whether the option optimized resources of Federal, State, professional and industry organizations;
- B. whether the option recognized individual program needs and abilities;
- C. whether the option promoted consensus on regulatory priorities;
- D. whether the option promoted consistent exchange of information between regulatory programs;
- E. whether the option promoted harmonization of regulatory approaches; and
- F. whether the option recognized State and Federal needs for flexibility.

The Working Group created a matrix to evaluate options for each Program Element against the evaluation criteria described above. These evaluation criteria appear as items A through F (corresponding to the criteria listed above) across the top of each matrix.

Each set of options begins by defining the current methods for accomplishing each program element. Row 1 of each matrix represents a baseline from which to evaluate other options. Subsequent rows represent other options identified for each program element. "0" means the option was rated equivalent to the existing method or option; "+" means the option was rated as an improvement for the specific criteria; and "-" means the option was rated as less desirable than the existing method or option.

Based upon the ratings of all options, the Working Group summarized the results into recommendations, which are summarized on pages 6.42 through 6.45.

## APPENDIX C

## Materials Licensing Guidance

### Options

1. No change from current. NRC develops licensing guidance for byproduct, source and special nuclear material licenses and requests input from AS, and AS also develop guidance for activities that NRC does not regulate and shares guidance with other States (CRCPD coordinates with States on some licensing guidance development).
2. NRC/AS jointly develop an agenda and priorities for developing licensing guidance and establish joint working groups to develop guidance.
3. NRC/AS jointly develop an agenda and priorities for developing licensing guidance and provide direction to an independent entity (CRCPD, ICRP, NCRP, HPS, professional organizations, etc.) that would develop the guidance documents.
4. No coordination between NRC and AS; NRC and individual AS develop guidance based on determined needs, including developing no guidance.
5. NRC/AS accept consensus standards for licensing guidance without further evaluation.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	+	+	+	+	0
3	+	+	+	+	+	0
4	-	0	-	-	-	0
5	+	+	0	+	0	0

**Recommendations:** NRC/AS jointly develop an agenda and priorities for developing licensing guidance. NRC/AS either use working groups to develop guidance or direct other organizations/entities to develop guidance when appropriate. This recommendation is a combination of options 2 and 3.

**Note:** One additional potential option was identified and dismissed by the Working Group. This option was to discontinue licensing certain categories of material (currently authorized under specific licenses) without substitution of another form of regulatory oversight. The Working Group eliminated this as a viable option and did not screen it. This potential option, if implemented, could have an adverse impact on public health and safety and is not risk-informed. Thus, it was found to be inconsistent with the strategic goal of protecting health and safety.

## APPENDIX C

# Materials Inspection Guidance

### Options

1. No change from current. NRC develops inspection guidance for its programs and AS develop guidance for their programs (recognizing that some States choose to adopt guidance in IMC 2800).
2. NRC/AS jointly develop guidance and establish priorities for this work; joint working groups would be assigned the task of developing guidance.
3. NRC/AS jointly establish priorities for inspection guidance development and either accept available consensus standards (after revision or approval) or contract other organizations to develop guidance under NRC/AS direction.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	+	+	+	0
3	+	0	+	+	+	0

**Recommendations:** NRC/AS should jointly establish priorities and develop inspection guidance. Joint working groups should be used to develop guidance. Alternatively, NRC/AS may also accept consensus standards (following review and revision, if needed) or contract with other organizations to develop guidance when not available and needed. This recommendation is a combination of options 2 and 3.

## APPENDIX C

## Materials Licensing and Inspection

*Alternative for States to Perform Licensing and Inspection  
for All Facilities Within Their Respective State*

Options:

1. No change from current. NRC regulates federal facilities and other entities (i.e., exempt distribution licensees) located within AS.
2. AS is granted statutory authority to perform licensing, inspection and enforcement for Federal facilities and other entities normally regulated by NRC (i.e., exempt distribution licensees and others).
3. AS are delegated authority (AS acts as NRC's agent) to perform licensing and inspection for Federal facilities and other entities normally regulated by NRC (i.e., exempt distribution licensees).

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	-	0	0	0	0	0
3	0	0	0	0	0	0

Note: Option 2 was found to result in increased resource utilization for regulatory agencies since Master Materials Licensees, large broad-scope licensees and certain multi-site licensees (i.e., USDA and some U.S. Army facilities) would no longer perform permitting and inspection activities for their facilities.

**Recommendation:** No recommendations for change. The Working Group requires input from OGC regarding legal issues that may be associated with AS either being granted statutory authority or delegated authority to perform licensing, inspection and enforcement for Federal and other facilities normally regulated by NRC.

**APPENDIX C****Performing Materials Inspection****Options:**

1. **No change from current. NRC performs inspections for all facilities authorized to possess/use AEA material in non-AS and at federal facilities in AS. NRC also performs inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS inspect facilities located in their respective States under existing programs.**
2. **NRC performs all inspections of all licensees in non-AS and AS.**
3. **AS perform inspections of facilities licensed by the AS, as well as at facilities licensed by NRC within their respective States. (This option does not take into account any legislative changes required for AS to perform inspections of federal facilities.)**
4. **Maintain the current inspection program (Option 1) and allow other entities to contract to perform inspections and report back to the appropriate regulatory agency (i.e., NRC or AS, depending on facility).**
5. **Maintain the current inspection program (Option 1) and allow licensees to perform self-inspections/audits (in lieu of inspection by regulatory agency) and report results to appropriate regulatory agency. Licensee self-audits conducted in lieu of inspection by regulatory agency would be determined by regulatory agency.**
6. **Require all States (non-AS and existing AS) to perform inspections of all licensed facilities located within their respective State.**
7. **AS performs inspections of AS-licensed activities and NRC-licensed activities when conducting routine inspections of commercial/academic entities that hold AS and NRC licenses. (No change in licensing structure, so no legislative changes would be required.)**
8. **Accept inspections/audits performed by other organizations and use these inspections to supplement AS/NRC inspection programs. AS/NRC would be selective in accepting results of such inspections. This could narrow the scope of AS/NRC inspections. (Examples of these organizations include other regulatory agency inspections or professional/industry organizations.)**
9. **Maintain current inspection program and supplement with use of "Centers of Expertise" for performing inspections of specific technical areas. Centers of Expertise could be either AS or NRC organizations, and would be jointly recognized by AS/NRC.**

## APPENDIX C

### Performing Materials Inspection

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	-	-	-	-	-	-
3	+	-	-	0	-	-
4	+	+	0	0	-	+
5	+	+	0	0	0	+
6	-	-	0	0	0	-
7	+	0	0	+	0	0
8	+	+	0	0	0	+
9	+	+	0	+	0	+

**Recommendations:** Maintain the current inspection program, but supplement the existing program with other options. NRC would perform inspections for all facilities authorized to possess/use AEA materials in non-AS and at federal facilities in AS. NRC would also perform inspections of general licensees and exempt distribution licensees located in non-AS and AS. AS would inspect facilities located in their respective states. Supplemental options would include: 1) allowing other entities to contract with NRC/AS to perform inspections and report results to the appropriate regulatory agency; 2) allowing licensees to perform self-audits which may be accepted in lieu of inspection by NRC/AS or reduce inspection effort by NRC/AS; 3) accept audits performed by other organizations and use these as a supplement to NRC/AS inspections to reduce inspection effort by NRC/AS; and 4) use "Centers of Expertise" to perform inspections of specific technical areas. Acceptance of licensee audits or audits performed by independent organizations to modify NRC/AS inspection effort would be determined by the appropriate regulatory agency in a selective manner. "Centers of Expertise" could be either AS or NRC organizations and would be jointly recognized by AS/NRC. This recommendation is a combination of options 1, 4, 5, 8 and 9.

**APPENDIX C****Performing Materials Licensing****Options:**

1. No change from current. NRC licensed AEA materials in non-AS, all federal facilities, exempt distribution, and SNM in greater than formula quantities. AS license AEA & NARM in AS and SNM in less than formula quantities.
2. \*Place all program requirements in regulations; require only notification or registration of materials licensees (name, location, materials to be used).
3. Maintain current program and supplement with contracted entities to perform some license reviews or portions of reviews for specific technical areas.
4. \*Licensees submit abbreviated license applications, indicating program commitments, and regulatory agencies review for completeness. This option would not require a detailed submittal of procedures to be used by the licensee.
5. \*Maintain the existing license application process, but regulatory agencies perform administrative reviews for completeness, detailed reviews of licensee procedures would occur during inspections.
6. AS license all facilities within their State (would require change in legislation, but this was not considered for this program element evaluation).
7. NRC licenses all facilities using AEA material.
8. Maintain current program but supplement with "Centers of Expertise" that could be used to perform reviews of specific technical activities.
9. Establish "Centers of Expertise," consisting of AS/NRC organizations, that conduct all license reviews, based on expertise of each organization.

\*Options 2, 4, and 5 were not evaluated further because they represent methods for performing materials licensing rather than organizations that may be assigned responsibility for materials licensing. The Working Group determined that a change in the level of licensing control should be considered by other working or task groups. This issue is currently being considered by the Phase II Byproduct Material Task Group.

**APPENDIX C**  
**Performing Materials Licensing**

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	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>
<b>1</b>	0	0	0	0	0	0
<b>3</b>	+	+	0	0	0	-
<b>6</b>	-	-	0	0	0	-
<b>7</b>	-	-		0	0	-
<b>8</b>	+	+	+	0	+	+
<b>9</b>	0	0	0	0	+	-

**Recommendation:** Maintain the current program and enhance both NRC and AS reviews through use of contracted entities or "Centers of Expertise" to perform some license reviews or portions of reviews for specific technical areas.

## APPENDIX C

# Reciprocity

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### Options

1. No change from current: NRC/AS conduct inspections of licensees when working in respective jurisdictions, NRC may choose to conduct inspections at AS licensee's home office (to review activities conducted in areas under NRC jurisdiction), and reciprocity is required and limited to 180 days in any calendar year.
2. NRC/AS do not conduct inspections of licensees working under reciprocity in their respective areas of jurisdiction and instead contact the licensing/regulating agency to exchange inspection histories.
3. NRC/AS require that the licensee establish an office or record location within the respective area of jurisdiction.
4. NRC/AS contract with appropriate regulating agency to conduct inspection of activities conducted under another agency's jurisdiction.
5. Abandon reciprocal recognition of NRC/AS licenses by other regulating agencies and require that licensees seek a specific license if they choose to conduct licensable activities in areas under another agency's jurisdiction.
6. Do not limit activities conducted under the provisions of reciprocity to 180 days.
7. Defer this issue to another working group.

The Working Group solicited comments from State stakeholders on this issue since NRC is the only regulatory agency that enters another agency's domain to conduct inspections of licensees working under reciprocity. (Note: AS cannot enter another State to conduct inspections of AS or NRC licensees working within their State.) Based on comments received, the Working Group determined that a recommendation for change in this area was not warranted at this time. The Working Group's conclusion would not preclude examination of this process under a separate initiative.

## APPENDIX C

# Technical Guidance Documents

Note: Technical guidance documents refer to guidance developed for use by licensees and industry in meeting regulatory requirements. Such guidance may be adopted by licensees to support their program requirements or licensing requirements for both NRC and AS.

### Options

1. No change from current. NRC and States develop such guidance or adopt guidance from Standards Development Organizations (SDOs), ICRP, NCRP, or allow licensees to propose guidance; regulatory agencies would review the documents to ensure that they meet agency/regulatory needs. IAEA or ISO guidance would also be considered.
2. Create a Technical Document clearinghouse for submission, evaluation and development of technical documents. The clearing house would publish the guidance in a catalog or comprehensive volume to make the guidance available to regulatory agencies. IAEA or ISO guidance would also be considered.
3. Allow SDOs to develop guidance and make the guidance available for use by regulatory agencies. (This option would not require acceptance review by NRC/AS.)
4. Contract development of guidance from SDOs based on NRC/AS needs.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	+	0
3	+/0	-	-	-	-	
4	+	0	+	+	+	0
5	-	+	-	-	-	+

5. NRC/AS develop guidance documents themselves.

**Recommendation:** Some organization would maintain a clearinghouse of technical documents evaluated and approved by the National Materials Program for use. Consensus on priorities, needs and recommendations for organizations to develop guidance should be jointly established by NRC/AS. This recommendation is a combination of options 1 and 2.

## APPENDIX C

## Training, Qualifications & Experience Standards

### Options

1. No change from current. NRC staff is trained and qualified in accordance with MC 1246, and AS develop and train staff in accordance with their program requirements. NRC/OAS continue to develop training programs as an option for States to use. Adequacy of training would be developed during IMPEP reviews.
2. Create central organizations to conduct all training.
3. Maintain Option 1 and create a clearinghouse of training ideas, resources and opportunities designed for or employed by regulatory agencies.
4. Allow licensees to provide training, on a voluntary basis, for specific technical issues/activities. Alternatively, consider contracting with licensees to train regulatory staff in specific technical areas/activities if voluntary initiatives by licensees are not available.
5. Maintain Option 1 and encourage regulatory agency exchange program to develop staff in specific technical areas.
6. Have the NMP coordinate and establish priorities for training, with NRC paying for training to "ensure uniformity." This was determined to be similar to Option 2 with regard to offering flexibility. In addition, it is based on an underlying assumption that by requiring one regulating agency to pay for all training, uniformity would be ensured because of contracting constraints and decisions made by a single agency.

	A	B	C	D	E	F
<b>1</b>	0	0	0	0	0	0
<b>2</b>	+	-	0	+	+	-
<b>3</b>	+	+	0	+	+	-
<b>4</b>	+	+	0	0	0	+
<b>5</b>	+	+	+	+	+	+
<b>6</b>	-	-	-	-	-	-

**Recommendation:** Maintain the current program and enhance with: 1) use of a clearinghouse of training ideas, resources and opportunities designed for or employed by NRC/AS; 2) allowing licensees to provide training, on a voluntary basis, for specific technical issues or consider contracting with licensees to train staff in specific technical areas; and 3) encourage a regulatory agency exchange program to develop staff in specific technical areas. This recommendation is a combination of options 3, 4, and 5.

## APPENDIX C

# Regulatory Program Reviews

### Options

1. No change from current; maintain IMPEP reviews.
2. Eliminate IMPEP reviews and do not replace with alternative; rely upon individual programs to function effectively.
3. NRC/AS implement self-audit programs, evaluating performance against common defined criteria and report to a National Materials Program entity that would be empowered to require corrective action to address deficiencies.
4. NRC/AS implement self-audit programs, evaluating performance against common defined criteria and report to NRC, with NRC empowered to require corrective action to address deficiencies.
5. NRC/AS jointly perform regulatory program reviews more fully utilizing "Centers of Expertise" concept.
6. NRC performs audits of all regulatory programs.
7. NRC/AS contract with an independent entity to perform audits of regulatory programs with results reported to the National Materials Program entity.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	-	-	-	+
3	+	-	-	-	-	+
4	+	-	-	-	-	+
5	+	+	0	+	0	0
6	-	-	0	-	-	-
7	0	-	-	-	-	-

**Recommendation:** Utilize team (NRC/AS) effort in conducting program reviews but fully implement use of "Centers of Expertise" to assist with team composition.

## APPENDIX C

## Regulatory Program for General Licensees - Regulatory Agency

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**Note:** This element refers only to the entity that would regulate general licensees and the general license program.

**Options:**

1. **No Change from current.** NRC and AS use different mechanisms for providing regulatory oversight for General Licensees, and the level of communication and contact with General Licensees varies widely among the existing regulatory programs.
2. **Return the full General License program to the NRC.**
3. **Regulatory agencies require that manufacturers of generally licensed devices maintain information on entities that have received generally licensed devices. This would include maintaining current information on where the device is located, what entity possesses the device, and information regarding radionuclides and quantities in an entity's possession.**
4. **An independent entity could be used to track and monitor use of generally licensed devices for all AS and NRC.**

	A	B	C	D	E	F
<b>1</b>	0	0	0	0	0	0
<b>2</b>	+	-	0	-	+	-
<b>3</b>	+	+	0	0	+	+
<b>4</b>	+	+	0	+	+	+

**Recommendation:** This needs to be examined concurrently with the following element. The Working Group recommends that this be discussed with the Steering Committee for consideration of whether a second working group should evaluate the General License program.

**APPENDIX C****Regulatory Program for General Licensees -Implementation**

Note: This element refers only to how the general license program is implemented.

**Options:**

1. No Change from current. NRC and AS use different mechanisms for providing regulatory oversight for General Licensees, and the level of communication and contact with General Licensees varies widely among the existing regulatory programs.
2. Modify the regulatory program and make all generally licensed devices exempt from regulation.
3. Modify the regulatory program and make all generally licensed devices specifically licensed items.
4. Staff each agency (AS and NRC) sufficiently to implement a general licensee program (this does not consider pending implementation of the registration program for NRC).
5. Require the manufacturers, who are specifically licensed, to monitor and record the distribution and transfer of generally licensed devices and provide reports to the existing regulatory agencies for review.
6. Require that generally licensed devices be leased and not sold. This would result in the manufacturers retaining some responsibility.
7. Require that manufacturers identify their customers' locations as an additional location of use on the manufacturers' specific licenses. This would result in the manufacturers retaining some responsibility.

Some of the options were rated by the Working Group; however, given the discrepancies in how these items are regulated and the number of questions regarding the basis for authorizing distribution and use of generally licensed items, the Working Group elected to discuss this element with the Steering Committee. The Working Group is seeking advice on whether this issue should be reviewed by a separate group.

## APPENDIX C

# Certification Programs

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### Options

Use CRCPD's G-34 Committee Certifying Entity process as an example (with minor modification) of how an element of a National Materials Program could work. Evaluate successes and problems identified by G-34 during initial implementation of the process, and document input received from G-34 with the working group's report.

## APPENDIX C

# Rulemaking

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### Options:

1. No change from current. NRC establishes rulemaking agenda, drafts the rule (with AS participation & input for some rules), establishes compatibility category and requires implementation. CRCPD working groups modify NRC rules to adapt for state use. CRCPD drafts rulemaking for non-AEA materials, and States usually adopt these rules. States may also draft rulemaking as needs are identified.
2. NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using "Centers of Expertise" where possible .
3. NRC/AS jointly develop a rulemaking agenda, but NRC drafts rules.
4. NRC/AS jointly develop rulemaking agenda, but NRC and States draft rules independently.
5. NRC/AS jointly develop a rulemaking agenda, but an independent entity (NCRP, HPS, CRCPD) drafts rules for NRC and AS to adopt. (NMPWG determined that this would not optimize resources because of the complications involving contracting the entity.)
6. AS jointly develop a rulemaking agenda, and NRC and AS cooperate in drafting rules.
7. AS jointly develop a rulemaking agenda, and NRC drafts rules.
8. AS jointly develop a rulemaking agenda, and states draft rules independently.
9. AS jointly develop a rulemaking agenda, and an independent entity drafts rules for NRC and AS to adopt. (NMPWG determined that this would not optimize resources because of the complications involving contracting the entity.)

## APPENDIX C

**Rulemaking - cont'd**

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	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	+	+	+	+	0
3	0	0	+	0	0	0
4	-	+	+	-	-	+
5	-	0	+	0	0	0
6	+	0	+	+	+	0
7	0	-	+	0	+	+
8	-	+	+	-	-	+
9	-	0	+	0	0	0

**Recommendation:** NRC/AS jointly develop a rulemaking agenda and establish a cooperative group to draft rules, using "Centers of Expertise" where possible.

## **APPENDIX C**

# **Information Infrastructure**

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The Working Group identified the following type of information as necessary to support a National Materials Program

- **Incidents and Events**  
Used for identification of Generic Safety Issues and to track performance
- **Number and Type of Licensees**  
Specific and General licensees
- **Sealed Source and Device Registration Sheets**
- **Escalated Enforcement Actions**
- **Regulations**
- **Licensing and Inspection Guidance**
- **Radiography Certification Process**  
For both individual radiographers and States/Organizations approved for certification
- **Directory Information**  
Identifying regulatory agencies, individuals and addresses
- **Service Providers**  
Waste brokers, recycling organizations/facilities, and sealed source recovery services
- **OSTP procedures**
- **Technical Guidance documents**
- **Program Information (such as provided in OSTP letters)**
- **Training Information (provided by NRC and other organizations)**
- **SNM database**

## APPENDIX C

### Information Infrastructure

The following information systems are currently maintained, but to serve a National Materials Program effectively, they should have linked access through websites.

<b>Information</b>	<b>Maintained by</b>
Rulemaking	NRC, SSRCCR, States
Radiography Certification (States/Organizations approved as certifying entities)	OSTP
Sealed Source and Device Registration	NRC
Licensing and Inspection Guidance	NRC, State
Directory Information	HPS, CRCPD, STP
Services	CRCPD, some States
OSTP Procedures	STP, some States
Technical Guidance Documents	NRC
Program Information	STP, NRC, States
Training	NRC, HPS, CRCPD, States

## Appendix C

# Incident/Event Response

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### Options

1. No change from current. NRC maintains centralized information and communication systems to support receipt of event reports from NRC licensees and AS. These systems are also used to facilitate communication between various State and Federal organizations regarding events that occur nationwide. NRC establishes processes with other Federal and State agencies to support interagency communication and response to events of mutual interest. NRC facilitates contact between AS and Federal agencies regarding events of mutual interest when needed, although AS may contact Federal agencies for assistance independent of NRC. NRC coordinates event response with other Federal agencies when needed, for both AS and NRC licensees. AS report events to NRC, and NRC determines criteria for reporting event information in public information systems. NRC compiles data for AS and NRC licensee events that meet Abnormal Occurrence criteria and produces an annual report for Congress.
2. AS independently establish and maintain information and communication systems capable of linking with NRC's system, and States upload data required to support a national event reporting database (with public access equivalent to the current systems). AS become responsible for soliciting support from Federal agencies, independent of NRC, through direct contact with the appropriate Federal agency. Any costs incurred as a result of Federal assistance would be borne by the AS. AS work independently to coordinate event response by multiple States and agencies when incidents or events involve multiple regulatory jurisdictions. AS submit information directly to public information systems in accordance with criteria established by NRC. NRC compiles data for AS and NRC licensee events that meet Abnormal Occurrence criteria and produces an annual report for Congress.
3. NRC and AS receive event notifications and respond independently. Each regulatory agency maintains information and communication systems as deemed necessary to support individual agency functions. No centralized event notification/reporting database exists. Responsibility for coordinating communications and response for events that cross jurisdictional boundaries would rest with the affected agencies. AS submit annual reports of events that meet Abnormal Occurrence criteria to NRC and NRC forwards State reports to Congress collectively with NRC's annual report.
4. NRC and AS jointly establish and maintain an event reporting information system that is accessible to the public. (This would not necessarily replace internal systems used by States or NRC.) NRC and AS review and establish criteria and procedures for posting event reports in public information systems. NRC and AS jointly establish and maintain communications networks to facilitate coordinated communications and response, at State and Federal levels, to events for which an AS may need Federal assistance and those which cross jurisdictional boundaries. NRC and AS collaborate on producing an annual report on those events that meet Abnormal Occurrence criteria.

## Appendix C

## Incident/Event Response - cont'd

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	0	-	-	-	-	0
3	+	+	-	-	-	+
4	+	0	+	+	+	0

**Recommendations:** Maintain certain aspects of the current system, i.e., use of a centralized public event reporting system, consolidated reports to Congress and coordination of contacts between Federal and State agencies, with enhancements. Enhancements would include joint development of guidance and procedures for posting event reports to public information systems and AS assuming greater responsibility for entering event data in public systems. Continued coordination of event response between NRC and AS when necessary would facilitate prompt notification of all affected parties for events which cross jurisdictional boundaries or involve generic safety concerns. AS would also assume greater responsibility for preparing input for the annual Abnormal Occurrence report. This recommendation is a combination of options 1 and 4.

## Appendix C

# Generic Assessment for Events

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### Options

1. No change from current. NMSS reviews incoming event reports (ENs, PNOs and MRs) and discusses the reports and related information with regional counterparts. Information is developed for each event through interactions with regional and OSTP staffs who, in turn, have gathered additional information from NRC licensees and AS counterparts to support generic risk/safety assessments. NMSS also uses information from the NMED database, Department of Energy weekly reports and other operational data to support weekly reviews by a Generic Assessment Panel (GAP) consisting of NMSS managers and staff. The GAP makes decisions regarding significance of the issue and forwards the issue to a lead division for review, which may result in a short-term follow up action, or recommends that the issue be discussed during a monthly briefing with senior NMSS management. Monthly operational event briefings are supported by NMSS, regional and OSTP staffs, with occasional support from AS staffs. Senior NMSS management determines whether significant issues should be considered for long-term action, such as revision to existing guidance or rulemaking. Events requiring long-term actions are tracked for implementation status by NRC.
2. The NMSS regional coordinator(s) works with regional counterparts to develop information to support generic risk/safety assessments from existing sources (i.e., licensees, NMED, AS staff, and other operational data sources). Regional staffs work with AS representatives as needed to develop information about events reported by AS licensees. The GAP conducts weekly event reviews, with support from regional and HQ staffs, and determines whether an event should be assigned to a lead division for review (events of lesser significance which may require short-term action) or referred for briefing at the monthly Operational Events briefing. Monthly Operational Event briefings are supported by NMSS and regional staff. Senior NMSS management determines whether significant issues should be considered for long-term action, such as revision to existing guidance or rulemaking. Events requiring long-term actions are tracked for implementation status by NRC.
3. NRC regional and NMSS staff develop information relating to events reported by NRC licensees and other operational data to support generic risk/safety assessment. NRC regional and NMSS staff and managers conduct generic risk/safety assessment (this may be done using the GAP process) for NRC licensee events. AS develop information relating to events reported by AS licensees and conduct generic risk/safety assessments. NRC and AS determine which of their licensees' events should be reviewed for potential short-term action, based on potential generic implications, and which events are significant enough to be considered for long-term action based on common criteria. Short-term actions are implemented by the NRC and AS, but the substance of the action and information concerning the event is shared between AS and NRC. Information relating to significant events identified as candidates for long-term action is reviewed monthly during a joint Operational Events briefing in which AS and regional staff provide input regarding their respective events and perspectives on appropriate long-term actions. NMSS determines what long-term action should be implemented (with input from AS and regions) when NRC has the lead for implementing the action. NRC would track the status of implementation for these actions. AS could implement actions within their respective programs, as deemed appropriate.

## Appendix C

### Generic Assessment for Events

4. NRC regional and NMSS staff and managers conduct generic risk/safety assessment (this may be done using the GAP process) of events reported by NRC licensees. AS develop information relating to events reported by AS licensees and conduct generic risk/safety assessments. NRC and AS independently determine which of their licensee's events should be reviewed for potential short-term action, based on potential generic implications, and which events are significant enough to be considered for long-term action. Each agency provides recommendations on proposed actions (i.e., indication that there is no generic implication, draft Information Notice or recommendation for rule change) to NMSS, which serves as a point of contact for monthly Operational Events briefings. Recommendations for action are reviewed jointly (NMSS, regions and AS) during the monthly briefing and a decision is reached on the appropriate course of action.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	0	0
3	+	0	-	+	-	+
4	+	0	+	+	+	0

**Recommendations:** Maintain some elements of the current program with enhancements, including: 1) have AS assume greater responsibility for generic assessment and for drafting proposed actions; 2) have AS assume a more active role in making decisions on appropriate responses to significant generic issues; and 3) seek broader input in decision making for long-term actions. Elements of the existing program that would be retained include NRC internal use of a GAP process and centralized review of proposed actions for both short- and long-term. This contributes to consistency in regulatory approach over a period of time and allows all parties an opportunity to participate in decision making. This is a combination of options 1 and 4.

## Appendix C

# Materials Research

### Options

1. NRC conducts or contracts research projects with costs passed through to NRC licensees. Products of these efforts are generally used to develop generic guidance or, less frequently, to address license-specific issues. Products are public documents and are therefore available for the benefit of AS regulatory programs and licensees, as needed. Research products developed by AS generally benefit State licensees and funding mechanisms are determined in accordance with State requirements.
2. AS continue to identify and fund research activities according to each AS's priority or need. NRC continues to identify and fund research activities according to its priorities or need. AS and NRC make the research products available to all through a centralized information "clearing house" for the benefit of all regulatory programs and licensees.
3. AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

	A	B	C	D	E	F
1	0	0	0	0	0	0
2	+	0	0	+	0	0
3	+	0	+	+	+	+

**Recommendation:** AS and NRC identify research priorities and needs and jointly prioritize common research activities on a national level. Specific individual needs could continue to be funded and carried out as is currently done. Joint, collaborative work could be funded through shared resources, and product scope and acceptance would be jointly determined. For those research projects representing emerging needs for several parties, funding and resource expenditures could be pro-rated for regulatory programs, based on the number of licensees that might benefit from the research product.

## Appendix D

# Relative Decision Matrix

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The decision matrix is a tool decision-makers can use to assist them in solving problems with multiple, and often competing, evaluation criteria or options. This decision tool is taught at Harvard University and is used among many groups including federal agencies such as the Department of Agriculture and the United States Army. The decision matrix software used by the Working Group was developed for use at the Combined Arms and Services Staff School (CAS<sup>3</sup>) at the U.S. Army Command and General Staff College, Fort Leavenworth, Kansas. The program author was a 1997 graduate of CAS<sup>3</sup>. The program is considered freeware and is intended for dissemination throughout the U.S. Army.

The Working Group used simple non-weighted decision matrices to evaluate the program elements. The Working Group used a "Relative Value" decision matrix to compare all of the final options for a National Materials Program against weighted criteria. The matrix reveals that the logic used by the Working Group was sound when the Working Group recommended the Alliance Option.

The purpose of this appendix is to explain how a decision matrix works and how it can be used in making decisions. A decision matrix compares available options against chosen evaluation criteria that all of the options must meet. Usually in a decision matrix, one criterion is more important in the decision making process than all of the others and a weight factor is assigned to the criterion. For the National Materials Program, protecting public health and safety is the most important evaluation criterion considered. All other criteria being evaluated follow in order of priority and are assigned a weighting factor in the pairwise comparison chart, with the larger values having the most weight. The assignment of weighting factors will make some evaluation criteria more important and some less important. The pairwise comparison chart of the decision matrix process is a structured approach that establishes criteria weights and then applies these weights within the decision matrix. A discussion of the pairwise comparison chart is detailed below.

A basic decision matrix shell is shown in Figure 7.1. Evaluation criteria are shown along the top of the matrix. By convention, evaluation criteria are shown in order of descending weight from left to right in the matrix. Options are shown along the left side of the matrix.

The decision matrix program calculates the totals of each option and shows the values in the far right column of the matrix. Within the decision matrix the lower values are better. The program also re-calculates the option totals whenever a value is changed. The type of matrix selected (Relative Value (RV) or Multiplication) and the Consistency Ratio is shown at the bottom right of the matrix.

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# Relative Decision Matrix

Figure 7.1

Weight	W1	W2	Total
Criteria			
Option			
	RV1	RV2	Total RV
	RV1	RV2	Total RV

Type of Matrix: Relative Value  
 Less Is Better  
 Consistency Ratio =

Either a relative value matrix (RV) or a multiplication matrix can be used for the decision making process. The relative value matrix is the easier of the two methods to use. It is the method of choice when evaluating criteria that do not have a real number values associated with the criteria, i.e. comparing intangibles such as protecting public health and safety, improving public confidence or promoting consensus.

The multiplication matrix is more accurate and used when comparing the magnitude of difference between measurable values. For example, when comparing different types of cars one may be interested in purchasing, a multiplication matrix may contain criteria such as a comparison of actual miles per gallon, cost of the vehicle, cubic feet of cargo space, and mean time between maintenance. This method cannot be used if the Evaluation Criterion cannot be expressed with a numerical value.

The type of matrix used for the Decision Matrix in Section IV is the relative value matrix. This matrix ranks the option based on the value obtained by ranking each option against each of the evaluation criteria. The best option for a particular criterion is assigned a value of one (1). The remaining options are then ranked, ordering them within that evaluation criterion. If two or more options have the same value within a given evaluation criterion, their rankings are averaged and the average is assigned to each of the options. For Example: Two options are tied for the 2nd and 3rd ranking.  $((2+3) / 2 = 2.5)$  Therefore 2.5 would be assigned to the two options and the next option would be assigned a value of four (4), etc.

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# Relative Decision Matrix

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Each relative value is put in the appropriate box corresponding to that combination of option and evaluation criterion. The relative value method computes the total for each option by adding the products of each relative value of the evaluation criteria multiplied times the evaluation criterion's weight for each evaluation criterion along an option row as follows:

$$(RV1)(W1) + (RV2)(W2) + \dots + (RVn)(Wn) = \text{Total REL VAL}$$

Where:  $RVn$  = Relative Value for the assigned value of the  $n$ th Evaluation Criterion

$Wn$  = Weight of the  $n$ th Evaluation Criterion

The pairwise comparison is the technique used to translate a comparison of the relative importance of the evaluation criteria into numerical values and then a mathematical model determines an appropriate weight to accurately reflect the logic. The pairwise comparison lends objectivity to what otherwise would be a simultaneous subjective ranking of many criteria -- something the human mind has difficulty doing. The completed pairwise comparison chart that was used for the relative value matrix in Section IV is shown in Figure 7.2 of this appendix.

To determine criteria weights using the pairwise comparison techniques the evaluation criteria are ranked in order of general importance. Factors and their values for criteria comparison are: (1) Equal, (2) Slightly Favored, (3) Favored, and (4) Strongly Favored. These are used to input the numerical *importance factor* into the chart by comparing each of the evaluation criteria against each of the other criteria. The following example shows the process by which one can determine the pairwise comparison:

## Appendix D

# Relative Decision Matrix

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EXAMPLE:

Which evaluation criterion (EC) is more important ... EC #1 or EC#2?

Answer: EC#1

By what *importance factor*?

Answer: 4 (Strongly Favored)

The *importance factor* 4 is entered in the box at the EC #1-EC#2 intersection.

	EC#2	EC#3	EC#4
EC#1	4	4	4
	EC#2	2	3
		EC#3	1

The evaluation of all pairs is continued until the chart is complete.

Next a logic check is conducted. In general, *importance factors* increase in value or are equal in value as you move from left to right along a row of the chart. If the *importance factors* do not consistently increase or remain the same as you move from left to right in the chart one of two conditions could exist:

(a) Evaluation criteria ranking are out of order: To solve this problem, reorder the order the evaluation criteria and repeat the pairwise comparison; or

(b) The logic of the pairwise comparison is incorrect. To solve this problem, the *importance factors* must be reevaluated.

An additional logic check is conducted within a given evaluation criterion. The values should decrease or remain the same as you move from top to bottom in the chart. Once all of the values are entered in the pairwise comparison chart, the computer calculates the weights for each of the evaluation criteria and imports those values to the decision matrix. The mathematical model that determines the criteria weighting is based on the Eigenvector method described in the monograph "Lecture Notes in Economics and Mathematical Systems." The methodology for solving the Eigenvalues for a specific Eigenvector is described in the book, Matrices and Transformations.

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# Relative Decision Matrix

Figure 7.2

Pairwise Comparison Chart

	Optimize Resources	Promote Consensus	Account for Individual Needs	Flexibility	Exchange of Information	Harmonize Regulatory Approaches	Public Confidence
Maintains Safety	4	4	4	4	4	4	4
	Optimize Resources	2	2	2	2	3	2
		Promote Consensus	1	1	1	1	1
			Account for Individual Needs	1	1	1	1
				Flexibility	1	1	1
					Exchange of Information	1	1
						Harmonize Regulatory Approaches	1

### Legend of Importance Factors

- 1 - Equal
- 2 - Slightly Favored
- 3 - Favored
- 4 - Strongly Favored

After the criteria weights have been determined, the program determines the consistency ratio. The consistency ratio uses a least squares method to measure how well the pairwise comparison values maintain a logical series of relationships.

The consistency ratio is shown as a percentage below the right side of the decision matrix. For this mathematical model, a consistency ratio of 95% or more means the logic of the pairwise comparison is acceptable using the weighting factors produced by the decision matrix program. If a consistency ratio below 95% results, an error box appears in the program. If a value below 95% occurs, the pairwise comparison must be re-evaluated for logic errors. The mathematical model that determines the consistency ratio is based on the method described in the book, Spreadsheet Modeling and Decision Analysis: A Practical Introduction to Management Science.

## Appendix D

# Relative Decision Matrix

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With a large number of evaluation criteria, the program model may not catch a single, obvious error in the pairwise comparison logic. This limitation of the model makes conducting the logic check very important, i.e. the user must ensure the pairwise comparison *importance factors* generally increase or are equal in value, as you move from left to right along a row of the chart.

Together with the consistency ratio, sensitivity analysis is a measure of the subjectivity of the decision matrix. Sensitivity analysis identifies the degree to which the decision matrix results are subject to change with only small changes in the evaluation criteria weights. A solution that is not sensitive to changes in weights provides the decision-makers with confidence that they have a valid solution. A solution that is "sensitive" to changes in weights is a red flag for the decision-maker. With a sensitive solution, the decision-maker must review the Pairwise relationships of the criteria to see if they really reflect the decision-maker's understanding of the relative importance of each criteria.

The program conducts sensitivity analysis by changing each Evaluation Criterion weight of 1.0 or more independently, within a range of plus or minus three points, and recalculates the matrix to determine whether the solution changes. The program resets the criterion weight to its original value and proceeds to analyze the sensitivity of the next Evaluation Criterion.

For example: For an Evaluation Criterion weight of 2.38, the program:

Sets the weight incrementally lower by hundredths of a point (e.g., 2.37, 2.36, etc.), it recalculates, and determines the weight where the solution may change. NOTE: In this example, the program does not set the value lower than 1.00 and therefore does not complete the calculation within the full range of -3.

Next the program sets the weight incrementally higher by hundredths of a point (e.g., 2.39, 2.40, etc.), recalculates, and determines the weight where the solution may change. The program stops calculating at the weight of 5.38 to complete the range of +3.

After this calculation is completed the program resets the weight to the original value of 2.38 and moves to analyze the next Evaluation Criterion.

The Sensitivity Analysis for the decision matrix used in Section IV, Recommendations, is shown in Figure 7.3.

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# Relative Decision Matrix

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Figure 7.3

### SENSITIVITY ANALYSIS

Maintains Safety	Not Sensitive
Optimizes Resources	Not Sensitive
Promote Consensus	Not Sensitive
Regulatory Approaches	Not Sensitive
Exchange of Information	Not Sensitive
Public Confidence	Not Sensitive
Account for Individual Needs	Not Sensitive
Flexibility	Not Sensitive

The decision matrix program calculates the totals of each option and shows the values in the far right column of the matrix. The program will re-calculate new totals whenever a value is changed.

The decision matrix is an important tool for making decisions more objective, especially when there are numerous evaluation criteria to be compared to a number of possible options. By using a decision matrix, or similar method, a high degree of confidence is built into the decision making process.

## Section VIII

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