

**ATTACHMENT 2**

**PROPOSAL FOR A PILOT PROGRAM  
TO TEST RULEMAKING ACTIVITIES  
UNDER AN ALLIANCE CONCEPT**

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# PROPOSAL FOR A PILOT PROGRAM TO TEST RULEMAKING ACTIVITIES UNDER AN ALLIANCE CONCEPT

## INTRODUCTION

In October 2000, the National Materials Working Group (WG) conducted a tabletop exercise to evaluate one aspect of the Alliance concept – setting national priorities. The exercise identified ways in which setting national radiation protection priorities could be improved. While only a tabletop, the WG concluded the exercise was a success. The WG was able to demonstrate that the concept of setting national, radiation, regulatory priorities by consensus is valid. It also demonstrated that such a forum could facilitate states working together to solve problems, even when the problem was not a national priority.<sup>1</sup>

The WG proposes to facilitate an additional pilot program to evaluate an additional concept of the Alliance process – rulemaking. This pilot would:

1. Evaluate how the Alliance may work for rulemaking; and
2. Obtain an early indication as to whether people are ready to buy into the Alliance concepts of centers of expertise and consensus. The proposal is to develop 10 CFR 41 through the Alliance.

## Current Process

Currently, regulations that have national impact are initially developed either by the states, or by NRC. Certification of radiographers and the 2-man rule are examples of regulations that were first developed by the states, and then by the NRC. When states take the lead, the NRC may or may not choose to follow. When the NRC has taken the lead, a state representative may participate in the process; the Conference of Radiation Control Program Directors, Inc. (CRCPD) will incorporate regulations as necessary for compatibility into the Suggested State Regulations for the Control of Radiation (SSR's); and states will adopt the regulation as desirable and/or necessary- some waiting until after the SSR's have been approved.

There are several problems inherent with the current processes:

1. Time delay - when the process is sequential rather than in parallel, the time to both develop and adopt the regulations is extended.
2. Compatibility is determined by NRC, rather than by consensus. This is especially problematic when states have not devoted resources to analyzing a regulation proposed for Category D compatibility, only to have the compatibility classification changed by the NRC at the time of adoption.

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<sup>1</sup> Washington agreed to take the lead on developing a licensing guide for PET facilities, even though it was not one of the top ranking priorities jointly identified between the states and the NRC.

3. Centers of expertise may not be consulted, or only consulted after the rule has been drafted.

### The Regulatory Process Under the Alliance

Under the Alliance concept, regulations are developed by centers of expertise through consensus. The process will be as follows:

1. Alliance meets and establishes priorities
2. Regulatory Change is identified<sup>2</sup>
3. Define the work product – e.g., regulation or guidance; scope depth, timeframe
4. Identify centers of expertise and establish working group
5. Set schedule
6. Working Group drafts rule, statement of consideration, regulatory analysis and proposes level of compatibility
7. Alliance's Standing Compatibility Review Group 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, go back to step 6
10. If there are no major changes to the rule and no changes to compatibility, the draft becomes a Suggested Regulation, and is distributed to Alliance with description of changes since the draft was reviewed.
11. Each agency adopts product, dependent on desire and compatibility, pursuant to its own administrative procedures.<sup>3</sup>

### Why Use Part 41 for the Alliance Rulemaking Pilot

Several factors favor conducting this pilot program with Part 41, rather than another Part in the regulations.

1. Part 41 affects a relatively small number of states and licensees. Therefore, if there are growing pains in implementing the new concept, they will be easier to deal with than if they affected all licensees and states.

2. Because some of the initial work has already been done, and states and stakeholders are aware of the issues, the Alliance could proceed faster, and thereby identify more issues before the final National Materials Program report is issued.

3. Because there are interest groups involved, it can demonstrate the feasibility of involving stakeholders in the development process.

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<sup>2</sup> A change may be identified as a national priority, or a some states agree to cooperate on one of their priorities that did not elevate to a national priority.

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

## Basic Assumptions

Under the Alliance, there are certain fundamental principals that will apply for the rulemaking pilot program.

- Regulations will be developed in partnership.
- Suggested Regulations will be established by consensus.
- Compatibility will be determined by a standing committee made up of Alliance members - both state and NRC.
- Not all centers of expertise may want to participate.
- Each agency must still meet its administrative procedures for the adoption of rules.

## OBJECTIVES OF PILOT

The pilot program to develop Part 41 will have the following objectives:

1. Provide the WG an opportunity to evaluate another of its program elements before finalizing its report. The WG recognizes it is unlikely a draft Part 41 will be finalized before its final report is due, but believes significant information can still be obtained, and the feasibility of another of the Alliance's functions can be evaluated based on real data.
2. Aid stakeholders in focusing on the Alliance and its proposed regulatory process. It will give all stakeholders a better insight, and provide better input into establishing a National Materials Program.
3. Identify possible changes that may be needed to the proposed regulatory process before it is applied to all regulations.
4. Develop a consensus document, in a partnership between the NRC, states and affected parties through early, full involvement.
5. Identify how the Alliance could interact with special interest groups, and learn their reaction to the Alliance concept.
6. Evaluate how NRC staff might relate to the Alliance concept. If NRC staff were not willing to participate at this stage, initiate discussions of why, and begin discussion of alternatives.
7. Compare projected costs of the current process to costs projected under the Alliance.
8. Reestablish a compatibility committee. Most states believed the results of the previous, complete compatibility review were valuable<sup>4</sup>.

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<sup>4</sup> Since the initial compatibility review in 19xx, compatibility decisions have reverted to the NRC, with disagreement between the NRC and the states. A standing compatibility committee could allow a consensus decision based on the principles of the original compatibility working group.

9. Compare the regulatory development process of the Alliance to that of the CRCPD.
10. Evaluate the relationship between the Alliance and the CRCPD.
11. Evaluate, based on initial progress, whether the Alliance would qualify as a Standard Development Organization.
12. Illuminate the role of the Core group and the NRC in rulemaking.

## REASONS FOR DELAY

A pilot program to adopt regulations under the Alliance concept has many advantages. However, arguments could be made as to why the Alliance should be further defined and approved by the Commission before changing the status quo. These include buy-in by the Commissioners; changing a regulatory process in midstream; inability to complete the process before the WG's report is due; confusion between the roles of the Alliance and CRCPD, and potential concern by licensees.

### Commission Buy-in

The commissioners might be concerned about the Alliance carrying this rulemaking forward before they have agreed to the concept of the Alliance. If licensees and/or the public do not have confidence in the process, it could reflect badly on the Commission.

The WG believes the pilot should be conducted because it will:

1. Help the Commissioners, as well as the WG, determine the feasibility of the Alliance concept before it has to be considered by the Commissioners; and
2. If no "fatal flaws" are identified, enable initial refinements to be made to the process before the Alliance concept is institutionalized.

### The Regulatory Process for Part 41 Has Already Started

One might argue that the Pilot should not address Part 41 because the regulatory process has begun, and a pilot should work on a regulatory change that has not been started.

It is an advantaged to the WG that the process of creating Part 41 has started. Prior to its final report, the WG would like to have as much real data as possible. The work on Part 41 to date has focused on identifying the issues and the players. This is similar to the Alliance's task of identifying priorities, and, to an extent, is what occurred with the tabletop exercise in October 2000. Because the priority has already been identified, the pilot can begin on the regulation, thereby proceeding further than the pilot could if a new topic had to be selected. As a result, more information can be obtained before the Commissioners will review the Alliance concept.

## Part 41 Will Not Be Completed In Time

The fact that Part 41 likely will not be completed before the WG submits its report to the Commissioners should not deter the pilot. As noted above, information will be obtained, and the more data that is collected, the better the recommendation to the Commissioners, and the more prepared the Commissioners will be to evaluate the Alliance concept.

## CRCPD Already Has An SR Committee That Will Address Part 41 Changes

The states and NRC have a history of adopting regulations under the status quo. The alliance will modify the current situation in order to make the process more consensus driven, and more of a partnership. Because the Alliance will use centers of expertise, and because the expertise generally rests with the NRC and those states represented on SR-13, it is expected that individuals who would have worked on the SR committee will instead work on the Alliance's working group. Further, completing the process under the Alliance concept, states and the Commission can compare the timing, costs, and quality of the product between the current process and the Alliance's proposed process.

## Licenses May Not Want the Alliance to Control Regulatory Development

Licenses may not feel comfortable having regulations developed by the Alliance,<sup>5</sup> either because they feel states lack the technical capabilities, or because they feel they might have less influence with an alliance of state and federal programs, than with the Commission.

Part 41 will involve many technical issues. Prior to the pilot, it is not possible to determine if there is sufficient technical expertise among NRC and state staff. If contractual support is required, the process will help define how contracts are funded and managed, and how that activity might affect both the organization and funding of the Alliance. This information is important, and should be determined before the WG completes its final report.

In regards to the ability of stakeholders other than the NRC and states to influence the outcome of the regulation, the WG believes the Alliance will produce a better regulation. There are two reasons for this belief. First, under the Alliance concept, stakeholders will be able to participate in the development of a regulation, rather than just commenting on the draft product.

Secondly, because Suggested Regulations will be developed and approved through consensus in a partnership, the final product will be less susceptible to influence on a few people or one agency.

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<sup>5</sup> The Alliance will develop Suggested Regulations. Each agency must adopt regulations according to their own administrative procedures.