

Comment Resolution Table: SECY-12-0112, Policy Statements on Agreement State Programs
 The NRC published the proposed policy statements in the *Federal Register* on June 3, 2013 (78 FR 33122)

| Comment No. | Commentor | Policy Statement | Location in the Document | Comment | Resolution |
|-------------|-----------|------------------|--------------------------|---|--|
| 1 | 1 | AC & AS | General | <p><i>Consistency- EnergySolutions</i> believes that as the NRC proceeds with proposed revisions to its policy statements on Agreement State Programs including "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and the "Statement of Principles and Policy for the Agreement State Program," the staff should work to ensure that at a minimum, the two policy statements are consistent. In essence, compatibility entails making sure the right regulations are in place, while adequacy is making sure they are met. As it is impossible to have one without the other, the existence of two separate policy statements distorts the integral relationship between compatibility and adequacy.</p> <p>Due to the significant level of overlap that exists between the two policy statements, and in the interest of simplicity and consistency, <i>EnergySolutions</i> proposes that the Commission combine the two policy statements into one policy statement.</p> | <p>Although there are two Policy Statements, the implementation of the two Policy Statements occurs in a seamless manner. NRC does integrate both Policies into their practices and having two separate policies does not change the consistency with which they are applied.</p> <p>At this time combination of the two Policy Statements is not part of the tasks on the current charter(s). At such time that the Commission directs the staff to consider combining the two Policy Statements, NRC staff will evaluate the plausibility.</p> <p>It is expected that the two policy statement be consistent. While the working group agrees there may be some merit for combining the policy statements, but not for the reasons provided.</p> <p>Reject: The request is beyond the scope of the policy statement update, The scope of the project</p> |

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| | | | | | includes adding source security in the determination of compatibility as well as updating the the policy statements for current practices. |
| 2 | 1 | AC & AS | General | <p>Roles and Responsibilities-<i>EnergySolutions</i> believes that the current policy statements do not adequately and specifically define the roles and responsibilities of the NRC and State regulatory agencies. Clearly defined roles and responsibilities are fundamentally important to determining the boundaries of who has ultimate responsibility, especially when Agreement States are found out of compliance with NRC criteria.</p> <p><i>EnergySolutions</i> proposes that the staff include a "roles and responsibilities" section in the updated policy statements to clearly define the relationship between the NRC and Agreement States.</p> <p>For example, the existing policy statements do not clearly describe how the NRC may provide program assistance in cases where an Agreement State cannot adequately fulfill its obligations.</p> | <p>Reject. Roles and responsibilities are defined throughout the policy statements, especially the <i>Statements of Principles and Policy for Agreement State Programs</i> policy statement. Roles and responsibilities are further defined in other documents that support these policy statements, i.e., management directives and procedures. In addition Management Directive 5.7, <i>Technical Assistance to Agreement States</i>, describes the role and technical response by the NRC in providing assistance..</p> |

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| | | | | <p>This has resulted in instances where undue burden has been placed on licensees due to a lack of timeliness in the States' ability to address emerging licensing issues. The updated policy statements should clearly:</p> <ul style="list-style-type: none"> • Define the conditions under which program assistance will be provided Set this threshold at a level that will ensure resources will be available in a timely manner in order to help States administer their regulatory responsibilities • Provide specialized technical assistance to Agreement States when addressing unique or complex licensing, inspection, and enforcement issues. | |
| 3 | 1 | AC & AS | General | <p>We recognize that to some extent there is a conflict between the concept of the NRC "relinquishing" its regulatory responsibilities and yet providing assistance. Some might even argue that in the event that assistance is needed, an Agreement State is failing an adequacy test. We do not agree with either of these notions. In fact, we believe there clearly are instances where the level of expertise is sufficiently high and the</p> | Reject: See comment #2. |

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| | | | | <p>need for resources at the state level is sufficiently rare, that the NRC would be undermining the intent of the <i>Atomic Energy Act</i> not to provide assistance.</p> <p>An example of an instance where an Agreement State specifically requested, and did not receive, NRC's technical assistance is a case involving the State of Utah's request for assistance with evaluations of Performance Assessments (PA) used by the State in licensing low-level waste disposal sites.¹ The State of Utah did not believe they had an adequate level of expertise or availability of resources to review the licensee's PAs in a timely and effective manner. The Performance Assessment Branch in NRC's Office of Federal and State Materials and Environmental Management Programs includes a number of highly qualified and experienced PA practitioners. Conversely, it is difficult if not impossible for any single state to maintain such expertise. If the NRC is going to maintain agreements with states to regulate low-level waste disposal, consistent with the provisions of section 274(i) of the AEA, the NRC should provide be prepared to provide assistance to states in this area. Doing so would leverage the NRC expertise; and</p> | |

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| | | | | <p>consistency in such reviews would clearly be in the nation interest.</p> <p><i>EnergySolutions</i> recommends that the Commission include within the roles and responsibilities section the circumstances and conditions when the NRC may provide programmatic assistance to an Agreement State, either upon their request or when they cannot adequately fulfill their obligations.</p> | |
| 4 | 1 | AC & AS | General | <p>In reviewing the past record of NRC taking enforcement² actions against agreement states, it appears such actions are inconsistent and often untimely. An example of NRC's lack of initiative to enforce their state agreements dates back to August 7, 2007 when the NRC informed the State of California of incompatibility issues between 10 CFR 61 and California Health and Safety Code section 115261, regarding the Licensing Requirements for Land Disposal of Radioactive Waste. In the ensuing time period, the Southwestern Low-Level Radioactive Waste Commission has repeatedly asked the NRC to take corrective action in this regard, to no avail.</p> <p><i>EnergySolutions</i> recommends that the Commission include within the</p> | <p>Reject: The policy statement <i>Statements of Principles and Policy for Agreement State Programs</i> does describe the action the NRC may take when a programs is found less than adequate and/or not compatible. The NRC does periodically evaluate California's radiation protection program for Agreement State materials during the Integrated Materials Performance Evaluation Program (IMPEP) review. However, since the State does not have a LLW program it is not evaluated during the IMPEP review. The IMPEP review does evaluate the State's regulations and has</p> |

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| | | | | <p>roles and responsibilities section the criteria and standards for taking action where an Agreement State does not meet the compatibility and adequacy requirements.</p> | <p>found these provisions are not compatible with NRC's regulatory program. The NRC has requested the State revise the regulations so they are compatible with the NRC's national program or have the State's Attorney General provide an explanation on how the regulatory provisions are compatible with NRC's regulatory program. Currently, the State has not complied with the NRC's request and there are limitations on what actions the NRC can take to require an Agreement State to change their regulations or legislation</p> |
| 5 | 1 | AC | General | <p>Compatibility- <i>EnergySolutions</i> believes that the Compatibility section of the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" is overly complicated, confusing, and in need of significant revision. The policy states that a compatible program should "...meet a larger nationwide interest in promoting an orderly pattern of regulation of radiation protection." We propose, however, that the compatibility categories listed do not support this worthy objective. Rather, the categories are more numerous than necessary, contribute to confusion rather than orderliness, and do not in sum contribute to a policy that meets the</p> | <p>Reject: This policy statement serves as guidance for both the NRC and the Agreement States. It affords the States a level of flexibility necessary to promote an orderly pattern of regulation. This has been proven by the consistent protection of public health and safety over the last sixteen years since this policy was adopted in 1997. Limiting the categories may place constraints on the States</p> |

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| | | | | nationwide interest. | <p>not intended by the original policy statement.</p> <p>The working group determined no changes to the policy statement will be made based on this comment.</p> |
| 6 | 1 | AC | General | <p>For Compatibility Categories A and B, the Policy states the Agreement State program elements "should be essentially identical to those of the Commission." The difference between A and B has nothing to do with what is required, but <i>why</i> it is required. To create separate categories to address why a standard should be "essentially identical"- whether it be because they address basic radiation protection standards or because of transboundary implications- is not justified. Agreement State programs also are required to adopt regulatory requirements listed as H&S, but not for compatibility (the logic of this exception regarding compatibility is not readily apparent). In essence, the NRC has created three different compatibility categories that all require the same thing, but for different reasons. We do not see any rationale for this approach. We propose that these three compatibility categories be consolidated into one category. While there may be different</p> | <p>Reject: The rationale to this approach can be found in SECY 95-112. In SECY 95-112 it was presented that the Commission would use a three component approach to compatibility. "First, the Commission will ensure that the basic radiation protection standards in 10 CFR Part 20, the dose limits in 10 CFR 61.41, and certain limited definitions are uniform across the country." (Compatibility Category A)</p> <p>"Second, the Commission will ensure the uniformity of a limited number of additional regulations essential to the facilitation of a consistent pattern for the regulation of activities having direct transboundary impacts." (Compatibility Category B).</p> |

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| | | | | <p>reasons that a regulatory requirement is required, these reasons could be articulated in support of one compatibility category. This would simplify the system with no loss in effectiveness.</p> | <p>“Third, the Commission will request the States to adopt other program elements but will give flexibility to Agreement States to adopt these additional elements in a manner that is consistent with their own program needs, as long as the State's program does not preclude a practice from occurring, and does not hinder the NRC's ability to assess regulatory issues on the national level.” (Compatibility Category C)</p> <p>It is also important to note that category H&S is not a compatibility category nor is it a matter of compatibility. This category is a matter of adequacy. As stated in the Policy Statement an adequate program should include those program elements not required for compatibility (emphasis added) but necessary to maintain an acceptable level of protection of public health and safety.</p> <p>The working group determined no changes to the policy statement will be made based on this</p> |

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| | | | | | comment. |
| 7 | 1 | AC | General | EnergySolutions proposes that the total number of compatibility categories be reduced to three (not including the NRC category). The first would be the same as the current category A. Under this category, states would be required to adopt regulations identical to those promulgated by the NRC. The rationales for requiring that they be adopted could include all of those currently listed under A, B, and H&S, and they could be listed in the Policy. | Reject: See commnet #6 The working group determined no changes to the policy statement will be made based on this comment. |
| 8 | 1 | AC | General | The second category would be for those regulatory requirements that the states should adopt, but for which the state standard may be more restrictive than the Commission program elements. This is similar to the existing Category C; but with one important distinction. <i>EnergySolutions</i> also proposes that in the event a state wishes to impose a standard that is more restrictive than the comparable NRC standard, it must provide a technical justification for doing so. This justification would be subject to review and approval by the NRC. NRC review is an important step that should be added to the process; it is important that the NRC confirm that the additional requirements imposed are merely discretionary enhancements and not | Reject: See commnet #6 The working group determined no changes to the policy statement will be made based on this comment. |

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| | | | | necessary to protect health and safety. Otherwise, the NRC undermines public confidence that its regulations, as well as those of the Agreement States, are sufficient to protect health and safety. A review process also would reduce the potential for states to adopt overly conservative provisions that makes the beneficial uses of agreement materials prohibitively expensive to discourage their use. | |
| 9 | 1 | AC | General | The final category would be for program elements that are not required for compatibility and would be the same as the current Category D. We could easily provide justification for the NRC to go even further and eliminate this category. The NRC frequently states that its regulations exist to protect health and safety. Presumably the Commission does not promulgate rules that it considers to be frivolous, so one is left to wonder why it would find it acceptable for Agreement States to on occasion ignore rules the NRC has determined to be sufficiently important to have promulgated in the first place. | Reject: See comment #6 The working group determined no changes to the policy statement will be made based on this comment. |
| 10 | 1 | AS | General | Good Regulation Principles- EnergySolutions applauds the NRC | Reject: The policy statement is not a |

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| | | | | <p>for its Principles of Good Regulation. They are sound, reasonable, and provide clear guidance for the regulators. We furthermore agree that it is reasonable for the NRC to encourage states to adopt a similar set of principles; but we are mystified by the inclusion of the following statement:</p> <p>“Failure to adhere to these principles of good regulation in the conduct of operations should be a sufficient reason for a regulatory program to self- initiate program changes that will result in needed improvements.”</p> <p>It is unclear why the NRC thinks that an Agreement State program that has failed to adhere to principles of good regulation would be sufficiently proactive to recognize this shortcoming or capable of correcting it on its own. We do not believe this statement is appropriate for inclusion in the policy and should be deleted. It is the responsibility of the NRC to recognize and require correction to Agreement State programs that are not performing adequately.</p> | <p>regulation. The good regulations principles further define the roles and expectations of the regulator.</p> <p>The working group determined no changes to the policy statement will be made based on this comment.</p> |

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| | | | | <p>We also believe it insufficient for the NRC to merely encourage states to adopt similar principles. Operating under such principles is an important characteristic of an effective regulatory body. Consequently, <i>EnergySolutions</i> recommends that the Commission stipulate that adopting principles of good regulation is necessary to demonstrate adequacy. We address the topic of Agreement State program adequacy in more detail below.</p> | |
| 11 | 1 | AS | General | <p>NRC response to Review Findings- Under Section 274 of the AEA, as amended, the Commission retains authority for ensuring that Agreement State programs continue to provide adequate protection of public health and safety. In fulfilling this statutory responsibility, the NRC is responsible for evaluating performance indicators of Agreement State radiation control programs through the systematic IMPEP performance evaluation process, to determine whether they are adequate and compatible prior to entrance into a Section 274b agreement, and to ensure they continue to be adequate and compatible after an agreement is effective. <i>EnergySolutions</i> believes that any update to the policy</p> | <p>Policy statements are general documents. Specific actions are further documented in Management Directives and procedures. The IMPEP process has proven to be a valuable tool to identify shortcomings in Agreement State programs and to assist States in program improvements.</p> <p>The working group determined no changes to the policy statement will be made based on this comment.</p> |

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| | | | | <p>statements should include a more rigorous and timely performance evaluation process. Furthermore, the value of identifying areas that need improvement can only be realized through prompt and clearly articulated actions by the NRC. <i>EnergySolutions</i> believes the existing policy statement relative to IMPEP review findings is too ambiguous and therefore makes enforcement of the agreement difficult. The NRC states in the existing policy statement that their actions will be based on a well-defined and predictable process and a performance evaluation program that will be consistently and fairly applied. To date, there are few examples where the NRC has taken actionable steps to enforce capability in spite of multiple instances where compatibility has been highly questionable. This again highlights the importance of having clearly articulated roles and responsibilities for the NRC and states relative to enforcement activities within the program.</p> | |
| 12 | 1 | AC | General | <p>Compatibility Category B – As described above, <i>EnergySolutions</i> believes that there is no logical basis for maintaining Compatibility Category B distinct from A. Because it is important to define what is</p> | <p>See comment #6 The working group determined no changes to the policy statement will be</p> |

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| | | | | to be included in each category, we offer our comments on the questions regarding this compatibility category. | made based on this comment. |
| 13 | 1 | AC | Definition of Significant Transboundary Implication | <p>Definition of Significant Transboundary Implication – We agree with NRC that the addition of the word particular is vague; however we do not believe that it should be replaced by "significant and direct. It is the need for uniformity nationwide that makes this definition important. It is important for the purposes of this definition merely that there be some health and safety impact. Each of the alternatives considered by staff serves only to add confusion, not clarity. We believe this definition, much the same as the compatibility categories themselves, are too often the subject of pedantic debates that do nothing to promote health and safety.</p> <p><i>EnergySolutions</i> proposes the following definition for Significant Transboundary Implication:</p> <p>"A significant transboundary implication is one that crosses regulatory jurisdictions, has an impact on health and safety, and needs to be addressed to ensure</p> | <p>Accept in part</p> <p>Based on the wide ranging comments on the definition of significant transboundary implication the working group recognizes that the term "significant transboundary implication" is open to wide interpretation. The working is proposing an entire rewording of the description of Compatibility Category B that eliminates the term significant transboundary implication. It is the working groups belief that the new description of compatibility category B is more succinct and utilizes plain language such that it is not open to vast interpretations.</p> <p>Changes have been made to the Policy Statement.</p> |

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| | | | | uniformity of regulation on a nationwide basis.” | |
| 14 | 1 | AC | Examples of Significant Transboundary Implication | <p>Examples- EnergySolutions proposes that examples are not necessary and should not be retained in the policy statement. Indeed, it is a significant challenge to identify NRC regulations that 1) cross regulatory jurisdictions, 2) have an impact on health and safety, or 3) ensure uniformity and still should <i>not</i> be required of the states. Some might argue that this sets the bar too low, but we believe it serves to illustrate the point that very few NRC regulations should not be imposed by Agreement States. If a regulation is not necessary for health and safety, then it could be argued that it is frivolous. If a state can pose a rationale for a stricter regulation, than it could be argued that the NRC has not taken appropriate measures. The NRC should focus more attention on ensuring that Agreement States effectively implement what the NRC has promulgated and less attention on enabling Agreement States to promulgate less effective radiation</p> | <p>Reject</p> <p>Based on all the comments received the majority of commenters requested that examples be added back in to the Policy Statement.</p> <p>Changes have been made to the Policy Statement.</p> |

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| | | | | protection standards or unjustifiably restrictive standards. | |
| 15 | 1 | AC | Economic factors Transboundary Implication | Consideration of Economic Factors – <i>EnergySolutions proposes</i> that it is entirely appropriate to consider economic factors in determining if a proposed regulation has significant transboundary implications. Presumably, when the NRC sees fit to promulgate a regulation, it already has made a determination that the new or revised regulation provides a real health and safety benefit. Thus, the question here is not whether or not it does in fact have such a benefit, but whether or not Agreement States should be required to adopt comparable standards. | Reject As stated in SECY 95-112 in a discussion on this very topic “Although the Commission recognizes the additional cost of business when dealing with different regulatory jurisdictions, the Commission does not believe that requiring an uniform national program solely for intrastate economic reasons is supported by the AEA.” Based on the previous Commission position and on additional comments received on the policy statement, no changes will be made based on this comment. |
| 16 | 1 | AC | Economic factors Transboundary Implication | In the event that the health and safety benefit is minor, the NRC may choose to give the states latitude to adopt or not adopt the regulation. In some instances, NRC may choose to allow states to be more restrictive; although, as we comment above, there should be limits on a state's ability to do so. But for the NRC to require the states | See comment 15 |

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| | | | | <p>to adopt standards that are "essentially identical," one of two standards should be met:</p> <ol style="list-style-type: none"> 1. The regulation addresses a "basic radiation protection standard" and is important to adopt for the purposes of protecting the health and safety of workers or the public (Compatibility Category A). 2. Adoption of varying versions of the regulation in different states would "jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." <p>Since NRC already has created a "health and safety" criterion in Category A, it seems only logical that the second case would be to address other factors, predominantly economic factors.</p> | |

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| | | | | <p>The most fundamental aspect of the "orderly pattern of regulation" is economic. Transportation regulations that changed at state boundaries would not create unacceptable radiation risks; they would impose unacceptable economic penalties. The main reason for having consistent nationwide transportation regulations is economic. It is important for health and safety reasons to have uniform, recognizable radiation hazard signs, but the burden of complying with signage and other transportation requirements that change from state-to-state clearly would be an unreasonable economic burden. It is reasonable for the NRC to consider economic factors because to do otherwise, the NRC itself would "jeopardize an orderly pattern of regulation."</p> | |
| 17 | 1 | AC | Transboundary Implication Alternate wording | <p>Limits to Compatibility Category B Program Elements- EnergySolutions believes that it is unnecessary for the Commission to limit this category to a specific number of elements. So long as "significant transboundary</p> | <p>Reject: As stated in SECY 95-112 in a discussion on this very topic "Although the Commission recognizes the additional cost of business when dealing with different regulatory jurisdictions, the Commission does not</p> |

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| | | | | implication" is clearly defined in the updated policy statement, the number of elements that are included in this definition will be the same regardless of the Commissions preference for a "small number of elements." There is no basis for predicting the outcome to the limits. This should be technically derived based explicitly on the definitions in the rule. | believe that requiring an uniform national program soley for intrastate economic reasons is supported by the AEA." Based on the previous Commission position and on additional comments received on the policy statement, no changes will be made based on this comment. |

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| 18 | 1 | Performance based compatibility | | EnergySolutions supports a graded approach for determining compatibility which ensures that states with facilities relevant to specific regulations comply, and excuses states without facilities from having to adopt unneeded regulations. As to whether, the promulgation of requirements should be by regulation, order, or license condition, EnergySolutions favors rulemaking as a general rule as it is a tool to obtain widespread stakeholder input. Orders and license conditions could and should be allowed when time is of the essence. | Comment to be considered under separate initiative. |

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| 19 | 1 | Performance based compatibility | | EnergySolutions proposes that the NRC hold a workshop with stakeholders to solicit comments on the performance based approach for determining compatibility. Such a workshop should be preceded by the drafting and publication of a specific description of what NRC means by such a performance based approach. | Comment to be considered under separate initiative. |
| 20 | 1 | Performance based compatibility | | <p>Conclusion – Given the current economic pressures that exist for both regulators and licensees, any resource investment made to improve the Agreement State Program should provide a more efficient pathway to meet health and safety performance goals. EnergySolutions believes the best way to achieve this is for the NRC to invest resources in developing a standard set of requirements for all states. This would serve three worthwhile objectives:</p> <ul style="list-style-type: none"> • Minimize the burden on licensees due to ambiguity in how each state applies program requirements <p>Allow states to focus limited</p> | Comment to be considered under separate initiative. |

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| | | | | <p>resources on implementation , rather than reconsideration of standards for the control of agreement material</p> <ul style="list-style-type: none"> • Reduce the burden on NRC for reviewing a wide variety of approaches that can and do affect both adequacy and compatibility | |

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| 21 | 1 | Performance Metrics | | <p>The requirements should be based on health and safety significant performance measures and any provisions that do not have a health and safety significance should not be promulgated.</p> <p>This approach requires confidence that the performance measures used to complete IMPEP evaluations are the right ones. Due to the level of variability that currently exists between state programs, this suggests that the best and right measures have not yet been identified. EnergySolutions recommends a re-evaluation of the Agreement State program IMPEP performance measures. We believe a workshop would be the most appropriate next step, one that broadly focuses on identifying areas of the Agreement State program that can be improved. The workshop should also specifically address technical aspects of the program such as performance metrics.</p> | Comment to be considered under separate initiative. |
| 22 | 2 | AC | General | The numbering system of sections and subsections in the proposed policy is confusing and should be revised. For example the Section named "1.0 Adequacy" has the same number assigned as "1.0 Compatibility". | Accept: The working group will revise the numbering system. |

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| 23 | 2 | AC | 1.0 Compatibly | <p>The proposed policy states the following: "Agreement State program elements may be more restrictive than Commission program elements; however, they should not be so restrictive as to prohibit a licensed activity." This language is confusing, in that licensed activities are determined by an Agreement State when it issues or amends a license.</p> <p>Similar language as used for Category D. (1), (2), and (3) should be used since these are important to the nationwide compatibility of regulations and licenses; and practices, as used in Category D. (2), is a more appropriate measure of nationwide compatibility.</p> | <p>Accept in part: The working group appreciates the comment; however, it is felt that the text as written is not confusing. Agreement States issue licenses based on regulations unless an exemption is issued.</p> <p>The language originally listed under Compatibility Category D describes compatibility in general and has been moved to the introductory paragraph on compatibility. The envisioned definition for Compatibility Category D has been added in place of the original text.</p> |
| 23 | 2 | AC | Section IV (1) | The phrase "significant and direct" is more appropriate for this definition. This is a much better understood metric than "particular". | <p>Reject:</p> <p>See comment 13</p> |
| 24 | 2 | AC | Section IV (3) | Examples should be maintained and broadened, particularly to address the issue of significant and direct impact on public health and safety. | <p>Accept:</p> <p>See comment 14</p> |
| 25 | 2 | AC | Section IV (4) | The description of Category B as written in "Section 1. Compatibility" of the proposed policy does not include the | <p>Reject:</p> <p>See Comment 13</p> |

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| | | | | words identified in Question 1: "has a (significant and direct) impact on public health and safety, and needs to be addressed to ensure uniformity of regulation on a nationwide basis". If this is added, then the goods and services should only apply to the part of the definition proposed as "one which crosses regulatory jurisdictions". | |
| 26 | 2 | AC | Section IV (5) | WCS agrees that health and safety should be the primary consideration. | Accept: No changes to the policy statement have been made. |
| 27 | 2 | Performance based compatibility | | WCS supports a performance based approach to determining compatibility. This approach would provide more flexibility for the Agreement State to implement compatible requirements, thus potentially reducing the time necessary for demonstrating compliance. A major rule making process that typically takes 2-3 years for the USNRC process and then another 3 years for the Agreement State is not an efficient process. | Comment to be considered under separate initiative. |
| 28 | 2 | Performance Metrics | | Regardless of the metrics used to evaluate the adequacy of an Agreement State's program, more attention needs to be placed on how the program regulates individual licensees. The primary focus of the current IMPEP evaluation appears to be focused on paperwork review and not how the Agreement state actually implements it program on individual licensees. Complex or problem licensees could be selected and examined in more detail regarding their license | Comment to be considered under separate initiative. |

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| | | | | conditions and the adequacy of inspections. This is particularly important if the USNRC adopts the more flexibility approach in question 3. There are many examples of both Agreement and USNRC material licenses that were not properly regulated and have become health and safety and financial problems that are not discovered until decommissioning. | |
| 29 | 3 | AS | General | <p>The ADDM requests that the IMPEP program be modifying to include the determination of the processing time for applications for new licenses and device registrations, and for the processing of amendments to existing licenses and registrations. We request that these statistics be summarized in IMPEP reports as the average time to complete actions, and the longest processing time for any individual action during the time period the report covers.</p> <p>In personal communications with IMPEP review team members they have informed us that processing time is a factor they evaluated, however we have never seen it referred to in a written report.</p> | Comment to be considered under separate initiative. |
| 30 | 4 | AC | Definition of Significant Transboundary Implication | The ORH proposes the following definition of "significant transboundary implication": "One which crosses multiple regulatory jurisdictions and would have a consequential impact on public health and safety if not directly and equally adhered to." | Reject: See Comment 13. |
| 31 | 4 | AC | Examples of Significant | Examples of program elements with significant transboundary implications | Accept: |

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| | | | Transboundary Implication | should be included in the Policy Statement. ORH recommends some of the examples include dose limits, patient release criteria, transportation requirements, requirements on portable devices such as those used in industrial radiography and training requirements. | See comment 14 |
| 32 | 4 | AC | Goods and services Significant Transboundary Implication | The movement of goods and services across regulatory boundaries should <u>not</u> be considered in the definition of significant transboundary implication. | Accept: The working group agrees with this comment and also determined that this position is supported by SEC-10-0105. No changes to the policy statement have been made. |
| 33 | 4 | AC | Economic factors Significant Transboundary Implication | Economic factors should <u>not</u> be considered when assigning compatibility to a program element. The ORH recommends allowing each Agreement State's legislative authority to set the economic impact limitations for their state. | Accept: See comment 15 |
| 34 | 4 | AC | Transboundary Implication alternate wording | The original text from the 1997 document should be retained. | Accept: See comment 17 |
| 35 | 4 | AC | Summary and Conclusions alternate wording | The ORH recommends that the wording regarding the expectation on the number of regulatory requirements that Agreement states will be requested to adopt in an identical manner be changed to read: "The Commission will minimize the NRC regulatory requirements that the Agreement States must adopt in an identical manner to those meeting the significant transboundary implication definition. These would include regulations under compatibility categories A | Reject The working group by 3-2 decision agreed with the majority of the comments requesting to return the language back to the original language from the 1997 policy statement. Changes to |

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| | | | | and B.” | the Policy Statement have been made to change the language back to the original language as published in 1997. |
| 36 | 4 | Performance based compatibility | | Agreement States should be allotted as much flexibility as possible to regulate the possession and use of radioactive material in a manner that has proven most effective for them. The ORH supports a performance-based approach in determining the compatibility of an Agreement State program. The ORH also recommends that if the NRC finds an Agreement State that is using non-standard methods to meet the compatibility objectives, then these methods should be shared by the NRC among the other Agreement States for review and consideration. | Comment to be considered under separate initiative. |
| 37 | 4 | Performance Metrics | | The current IMPEP process and metrics are appropriate. The process allows the team to review all the indicators and determine if the Agreement State is properly protecting the public health and safety. The ORH would only recommend changes to the IMPEP if it can be demonstrated that the process is not working as it was designed. The ORH, though, does recommend the following changes to the IMPEP: a) The Commission should require an annual audit be performed by the Agreement State and NRC programs which will be made available during the IMPEP. | Comment to be considered under separate initiative. |

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| | | | | b) The Commission should consider creating a full-time IMPEP team leader to ensure consistency for the process and reports. | |
| 38 | 5 | AC | Purpose | <p>In the Purpose section, we recommend changing the word "relinquishes" to "discontinues." Discontinue or discontinuance are the words used in both the AEA and each state agreement. We agree with the decision to use the term "physical protection" rather than the word "security." Physical protection of licensed material has always been a component of an effective health and safety protection program. For most of us, "security" of licensed material beyond that necessary and reasonable to protect public health and safety is not a part of our defined mission. Using the term "physical protection" better coincides with our health and safety mission.</p> <p>We agree with the decision to bring the definition of "program element" out of the footnote and into the text body. Definitions should not be in footnotes</p> | <p>Accept: Based on the receipt of several comments requesting the word discontinue be used instead of relinquish. Changes to the Policy Statement have been made.</p> <p>Regarding the rest of the comment we also accept the items mentioned, however, no changes to the Policy Statement have been made.</p> |
| 39 | 5 | AC | Background | <p>We appreciate the clarification of the wording in the second paragraph of the Background section. This is an example of differing interpretations. The original text was interpreted by some states to indicate that the Commissioners would not finalize a unilateral change in what staff submitted to them without first offering the change to the Agreement States for comment. That did not mean that the Commissioners' authority was in question. They still have</p> | <p>Reject 1st paragraph: While we agree that the Commission should have all pertinent information before making a decision, the Commission has the authority to render its decision without seeking additional input from stakeholders (including the Agreement States) outside</p> |

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| | | | | <p>the final say in what decision is made. It was only interpreted to mean that they would allow the Agreement States to comment on changes which they likely had never seen nor been offered the opportunity to comment on previously. We continue to believe that it would be prudent for the Commissioners to seek comments from the Agreement States before they finalize any unilateral decisions that affect Agreement State programs. However, this paragraph might be better placed in the Discussion section, perhaps as a closing paragraph. It seems as though it is better described as a discussion item rather than a background item.</p> <p>The sentence "The Agreement State should also ensure that its program serves an overall nationwide interest in radiation protection (the "compatibility" component)," raises some questions. An Agreement State is tasked with the radiation health and safety of the people in <u>their</u> state, not other states. We do not believe that states spend time and money on reinventing the wheel when it comes to good radiation safety policies, rules and practices. If it is working well for the NRC or another Agreement State, they will adopt the same policy, rule or practice. However, if an Agreement States finds that what is being used in another state or the NRC has not adequately addressed a radiation safety issue that may be unique to their state, they must have the flexibility to address the issue in a manner that</p> | <p>of the normal public comment period. No changes to the Policy Statement have been made.</p> <p>Accept 2nd paragraph: There is a disconnect between the first and second sentences in this section (1. Compatibility). The working group will include wording to also include Compatibility Category C. A change to the Policy Statement has been made.</p> |

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| | | | | serves the people of their state. The term "nationwide interest" may be unrelated to, or in rare instances, in conflict with, the mission of an individual Agreement State. | |
| 40 | 5 | AC | Compatibility | Under "Compatibility," please change the second sentence to read "Those program elements should be limited to regulation of radiation protection, protection standards and activities with significant transboundary implications." (Emphasis added). We also recommend you consider changing the third sentence of that paragraph to read "A compatible radiation safety program is one that does not create conflicts, duplications, gaps or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." (Emphasis added). | Reject in part: After discussing this comment and comment 94 the working group decided to rewrite this paragraph to clarify and simplify the paragraph. (Note: First and last sentence of paragraph was retained.) |
| 41 | 5 | AC | Significant transboundary definition | The definition of "significant transboundary implications" should include examples, but consider adding a rationale for each example. Also, adding the term "for example, but not limited to" would help indicate that any examples given are not, by themselves, enough to require a " B " compatibility, nor do the examples stated comprise an all-inclusive list. Regarding the definition of "significant transboundary implications," rather than using the term "particular" in the definition we would prefer "significant and direct," even though using "significant" to define "significant" is not ideal. "Significant transboundary implication" is not an easy term to define | Reject: See comment 13 |

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| | | | | or grasp. The word significant is a relatively vague term that is wide open for interpretation. While we understand that compatibility is not wholly determined by health and safety, we believe that health and safety does play a substantial role in compatibility because health and safety is the basis for any Agreement State program element. Therefore, we offer an option to replace "significant transboundary implications" with the term "significant health and safety issues which cross regulatory jurisdictions." From a radiation safety standpoint we already have set maximum exposure limits, and therefore we have a basis on which to determine what "significant" means. If the current term is maintained, we feel it is important to clearly define and explain the interpretation of "significant." | |
| 42 | 5 | AC | Goods and services | We do not believe that the movement of goods and services across regulatory boundaries should be a major factor in determining whether a program element should be classified as a compatibility category B. The recent change in compatibility from B to C for certain GL rule sections is an example of why Agreement States need the flexibility to address health and safety issues for the movement of goods and services across regulatory boundaries. | Accept: See comment 32 |
| 43 | 5 | AC | Economic factors | We also do not believe that economic factors should be considered when assigning compatibility to a program element. We prefer to allow each | Accept: See comment 15 |

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| | | | | <p>Agreement State's legal council to set the economic impact limitations for their state. Economic impact is a moving target, and is affected by a myriad of laws and other factors that vary from state to state. It is very unlikely that any state's legal council will allow such excessive economic impacts that it would prohibit a licensed activity. But what is considered excessive by one licensee or regulating agency may not be considered excessive by another licensee or regulating agency, so how do you set the standard?</p> | |
| 44 | 5 | AC | Compat B alternate wording | <p>The NRC has asked that specific comments be given regarding the text in the discussion of Compatibility B. The original text states "The Commission will limit this category to a small number of program elements that have significant transboundary implications." The alternative text states "The Commission will limit this category to program elements that have significant transboundary implications. The Commission expects that these will be limited in number." This alternative text was created on the premise that the original text somehow limited the Commission's authority. We believe that the original text from the 1997 document should be retained for a number of reasons. We believe the change trivializes the intent on the part of the Commission to give serious consideration before assigning a category B to a program element, and de-emphasizes the idea that Agreement States should be</p> | <p>Reject: See Comment 13</p> |

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| | | | | <p>given flexibility when addressing program elements. The current text stresses the importance of not being cavalier in the decision making process. We also believe the text change adds no real content to the intent of the paragraph, and, in fact, takes attention away from the intent, which is to assure that Commission staff understands and considers the gravity and implications associated with assigning a compatibility level B to a program element. The new text implies that there are a small number of times that the Commission needs to consider such implications as opposed to always considering them and then carefully deciding if it should be recommended to assign it as a B.</p> | |
| 45 | 5 | AC | Summary alternate wording | <p>Similar text is in the Summary and Conclusions section where the current text states "The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. At the same time, requirements in these compatibility categories will allow the Commission to ensure that an orderly pattern for the regulation of agreement material exists nationwide." The alternative text states "The Commission will identify regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. The expectation is that these requirements will be limited. Requirements in these compatibility categories allow the</p> | <p>Accept: See comment 35</p> |

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| | | | | <p>Commission to ensure that an orderly pattern for the regulation of agreement material exists nationwide." We again believe the original text from the 1997 document should be retained. The original text places emphasis on the Commission's effort to minimize unnecessary burden on the Agreement States ability to accomplish the same goals as the NRC program elements. This allows and encourages flexibility to use the most efficacious means to meet the goals of a program element.</p> <p>In both alternative texts the suggested changes do not place an emphasis on the Commission to carefully consider whether there are other possible options to meet the same goal. Rather the emphasis is placed on expecting that there will be a minimal number of times that they need to use careful consideration. Agreement States have often already dealt with the issues being considered by the Commission and have made decisions that work best for their licensees and staff. What works best for the NRC is not always what works best in all states. There are often more effective ways to address an issue. There is no evidence that the current wording in either of these instances has ever limited the Commission's authority. The Commission is not bound to any specific number in that the terms "small" and "minimize" are not defined anywhere as a number, and are strictly up to the interpretation of the Commission.</p> | |

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| 46 | 5 | AS | | In the third paragraph of the Purpose section, we recommend changing the word "relinquishes" to "discontinues." Discontinue or discontinuance are the words used in both the AEA and each state agreement. | Accept: The working group agrees and the change has been incorporated. |
| 47 | 5 | AS | | We recommend that you change the term "security measures" to more closely follow the "physical protection" of AEA material as part of public health and safety. This falls in line better with the Agreement States health and safety mission. | Accept: The working group agrees and the change has been incorporated. The working group added that for purposes of this policy statement, public health and safety includes these enhanced security measures physical protection of agreement materials. |
| 48 | 5 | AS | | The new text under the "Good Regulation Principles" section does not appear to be what one would expect in a policy statement. This is not a rule. As was stated earlier in this letter, "This Policy Statement is intended solely as guidance for the Commission and the Agreement States in the implementation of the Agreement State program." The use of the words "must" and "shall" in the proposed text seems too unbending and demanding for a guidance document. | Reject: "Must" and "shall" are used in the tenants of the principles not the implementation of the guidance. No changes were made based on this comment. |
| 49 | 5 | AS | | In the second paragraph under the "Compatible in Areas of National Interest" section we recommend changing the first | Accept with modification: Removed interstate commerce, and movement |

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| | | | | <p>sentence from "Such areas include those affecting interstate commerce, movement of goods and provision of services, security of Category 1 and 2 radioactive sources, and safety reviews for the manufacture and distribution of sealed sources and devices sold nationwide." to "Such areas include those affecting physical protection of Category 1 and 2 radioactive sources and safety reviews for the manufacture and distribution of sealed sources and devices sold nationwide." The movement of goods and services could be called interstate commerce, but the movement of goods and services is not a requirement for compatibility in and of itself.</p> | <p>of goods and provision of services. However, to further illustrate the "Compatible in Areas of National Interests" section, added but are not limited to, aspects of licensing, inspection and enforcement, response to incidents and allegations" Each of these areas are required for adequacy but also have program elements for compatibility.</p> |
| 50 | 5 | Performance based compatibility | | <p>The NRC staff is seeking additional input on whether a performance-based approach for determining compatibility of an Agreement State's radiation control program should be developed In general, we support giving the Agreement States as much flexibility as possible to regulate the possession and use of radioactive material in a manner that has proven most effective for them. The elements for an effective safety culture will vary from state to state and geographic area of this diverse country. An effective safety culture must take into consideration the social, cultural and economic circumstances surrounding the use of radioactive material.</p> | <p>Comment to be considered under separate initiative.</p> |

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| 51 | 5 | Performance Metrics | | The NRC staff is seeking additional input on whether: (1) a revised set of performance metrics could be used to replace, supplement, or expand upon IMPEP in determining adequacy of an Agreement State's radiation control program; and (2) a single holistic determination can be made that would accurately reflect the overall adequacy and compatibility of a program. We are not really sure what the basis is for question number 1. We believe the IMPEP program as it has been developed is far more effective in evaluating the adequacy of an Agreement State than the program it replaced. We do not see what is "broken" that needs to be "fixed" by revising the performance metrics. Regarding the single holistic determination, we do not believe that would enhance the IMPEP process. As it is now, if a program has a unique and effective way to handle a situation, they are recognized for their good practice. So, besides the discussion of any findings needing attention, the NRC already has in place a way of recognizing the good practices of a program. IMPEP is not, and should not be, a comparison between regulatory programs. Each Agreement State program is unique and should not be compared to other Agreement States or NRC regions. | Comment to be considered under separate initiative. |
| 52 | 6 | AC | Compatibility B Significant transboundary definition | In regards to "a significant transboundary implication" proposed definition of "one which crosses regulatory jurisdictions, has a particular impact on public health and | Reject: See comment 13 |

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| | | | | <p>safety, and needs to be addressed to ensure uniformity of regulation on a nationwide basis". WI endorses the Organization of Agreement State's proposal to replace "particular impact on public health and safety" with "negative impact on public health and safety." Removing the Agreement State's flexibility to address health and safety issues within state boundaries by being more stringent is one of the central issues involved in making a determination of "B" versus "C".</p> | |
| 53 | 6 | AC | Compatibility B Significant transboundary definition | <p>Compatibility "B" is the category between "A", requiring identical wording, ("for basic radiation protection standards meaning dose limits, concentrations and release limits"), and "C" which provides the Agreement States with the flexibility to be more stringent, ("should embody the essential program objective of the corresponding Commission program elements"). WI provides the following discussion on proposed and final regulations in order to illustrate when a "B" versus a "C" is appropriate. It is tempting from the federal perspective to decide that all regulations should be "uniform". However, this does not permit the Agreement States the flexibility to be more stringent and to develop an alternative, and possibly better, way to protect public health and safety. If the regulation in question does not affect or cross into another regulatory jurisdiction, (i.e. another Agreement State or an NRC regulated state), then preference should be given to determine the compatibility requirement as</p> | <p>Reject: See comment 13</p> |

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| | | | | <p>a "C".</p> <p>Example 1: Proposed Part 35 Wisconsin supports the designation of training elements in 10 CFR 35 as Compatibility "B". It is necessary for Agreement States to have essentially identical requirements for authorized users, authorized medical physicists, etc. because these individuals often cross state boundaries and use licenses from other jurisdictions as documentation of their training and experience. For example, States and the NRC all need to accept the same board certifications.</p> <p>On the other hand, medical event reporting requirements do not have significant transboundary implications because a particular medical event can only happen in a single jurisdiction. The reporting requirements are appropriately categorized as Compatibility C. It remains a State's responsibility to protect public health and safety. As long as a State's medical event reporting requirements capture the essential element of the NRC's provision, States must have the flexibility to gather additional information such as diagnostic errors or shorter reporting times. For prostate brachytherapy, Wisconsin is very interested in retaining a dose-based option for reporting medical events.</p> <p>Example 2: Final Part 37 Wisconsin supports the designation of sections in 10 CFR 37 as Compatibility</p> | |

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| | | | | <p>"B". Determinations made by licensees about individuals seeking unescorted access are critical to protect public health and safety and security. Before making any determinations a licensee will request information from outside entities, e.g. other licensees, previous employers, FBI background check, etc. An existing criminal history records check file may be transferred between licensees upon request and consequently crucial information crosses regulatory jurisdictions. The designation of Compatibility "B" for sections that outline what comprises an individual's background investigation and criminal history check ensures the quality and scope of the information. This allows for the transfer of reliable information and prevents the needless duplication of time and effort for licensee and regulator.</p> <p>At the same time, the section regarding the procedures for access authorization program requirements is appropriately designated Compatibility "C". These procedures do not have significant transboundary implications because they are unique and self-contained to each licensee's operational structure. Public health and safety is ensured by the State's performance based review of the licensee procedures.</p> <p>The State, from the vantage of performance evaluation, must have the flexibility to be more stringent if necessary to protect public health and safety.</p> | |

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| | | | | <p>Example 3: Proposed Part 61</p> <p>Wisconsin agrees with the following recommendation by the Standing Committee on Compatibility: "The SCC recommends that section 61.58 be designated as Compatibility Category C. Since the waste acceptance characterization will be site specific, the need for essential identical language would limit the ability for the Agreement State to have the needed flexibility to address the essential objectives of the requirement while addressing site specific conditions. As a Compatibility Category C designation, the Agreement State would have to adopt all the essential objectives of the section but could also adopt more stringent regulations that may be site specific. The revision should also include that NRC is retitling, revising and reclassifying the compatibility for section 61.58."</p> | |

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| 54 | 6 | AC | Significant transboundary definition Goods and services | <p>The "movement of goods and services" is overly broad and not the correct criteria to determine if a regulation "crosses boundaries" or has transboundary implications. The examples used before were "transportation regulations and sealed source and device registration certificates." In addition, "services" may not even be applicable if no radioactive material is involved. One should look at the regulation from the perspective of whether it is internal to the state, as in the management of general licensees, or has the potential to create a problem such as when a physician authorized user in one jurisdiction relocates across a state line.</p> <p>Recommendation: Delete the phrase "movement of goods and services" from the text of "Statement and Principals and Policy for the Agreement State Program, 4. Compatible in Areas of National Interest" and refrain from using it in the Policy Statement on Adequacy and Compatibility of Agreement State Programs, especially when dealing with Compatibility "B".</p> | <p>Accept:</p> <p>See comment 32</p> |
| 55 | 6 | AC | Economic factors Significant transboundary definition | <p>No, economic factors should not be a consideration in making compatibility determinations. Health and safety should be the primary factor. Cautionary language is proposed that the Agreement State cannot do something so extreme that the effect would be to prohibit the use of radioactive material. This concept of not</p> | <p>Accept:</p> <p>See comment 15</p> |

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| | | | | doing something to effectively preclude an activity is addressed in "Statement and Principals and Policy for the Agreement State Program, 5. Flexibility." WI agrees with this proposed language. | |
| 56 | 6 | AC | Original language Significant transboundary definition | Wisconsin supports retaining the original 1997 Policy Statement language "The Commission will limit this category to a small number of program elements (e.g. transportation regulations and sealed source and device registration certificates) that have significant transboundary implications." We agree that the original language in the 1997 version of the Policy Statement was not intended to dictate the Commission's authority but rather was to remind those staff proposing designations of compatibility B to the Commission for consideration that program elements of this designation should be few as opposed to many and should only involve significant transboundary implications. | Reject: See comment 13 |
| 57 | 6 | Performance based compatibility | | Consideration of a performance based approach in determining Agreement State compatibility Yes, Agreement State compatibility should be performance based. This determination should be based on the Agreement State's demonstration that the intent of the regulation is met. Typically this is accomplished through license condition(s) as was done for Increased Controls licensees. There are other examples such as the definition of radioactive material. In many Agreement States the term "radioactive material" includes byproduct | Comment to be considered under separate initiative. |

Comment Resolution Table: SECY-12-0112, Policy Statements on Agreement State Programs
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| | | | | <p>material. Therefore, when the Nuclear Regulatory Commission expanded the definition of byproduct material, it did not impact the Agreement States who already had an expanded definition because they used the term radioactive material.</p> | |
| 58 | 6 | Performance Metrics | | <p>Performance based metrics in the adequacy determination of an Agreement State program.</p> <p>A performance based approach to adequacy or "flexibility to be more stringent" does not mean that health and safety is compromised. There is a pervasive attitude that "flexibility" is needed because of short-comings of Agreement States. This is demonstrated by the proposed new language that states the NRC should "consider the limitations of an Agreement State program and provide increased flexibility without compromising public health and safety". This is an incorrect interpretation. The use of "flexibility" should not imply that the Agreement State is running a degraded program due to lack of sufficient resources.</p> <p>A performance based approach <u>does</u> mean that the state may have developed a different approach or method. If the Agreement State is meeting the intent of a certain program element, then they should not be "marked down" for developing an approach that does not exactly match the NRC. An example of using a performance</p> | <p>Comment to be considered under separate initiative.</p> |

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| | | | | based approach was the development of certification for industrial radiographers in Texas. This turned out to be a good approach and was eventually adopted by the Nuclear Regulatory Commission and the Agreement States. If this is the meaning of "performance based" in the adequacy determination then Wisconsin supports it. States should be encouraged to develop new initiatives when issues potentially affecting public health and safety are identified. The current system of "adequate", "adequate but needs improvement" or "inadequate" is sufficient. | |
| 59 | 7 | AS | | <p>Paragraph III. Discussion</p> <p>I. The subparagraph entitled "Statement of Principles and Policy for the Agreement State Program", the phrase "nuclear materials" is used twice. However, this term seems to be used as a generic term describing all types of materials that may be radioactive and that are regulated. Also, it does not seem to be used later in the Policy Statement.</p> <p>It is recommended the term be replaced with the commonly used term of "agreement material".</p> | Accept: Nuclear material was changed to Agreement material |
| 60 | 7 | AC | | Paragraph IV. Proposed Revision to Policy Statement on Adequacy and Compatibility of Agreement State Programs | Accept in part: The modification was not made to the Policy Statement on Adequacy and Compatibility of Agreement State |

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| | | | | <p>I. The subparagraph entitled "Background" introduces the fundamental concepts of "adequacy" and "compatibility" and directs a cooperative effort between the Commission and Agreement States in formulating standards to assure the "standards will be coordinated and compatible." However, the level of cooperation in the development and implementation of standards seems to be dictated "top down" rather than a truly cooperative effort. It appears the Commission establishes the "standard" and the Agreement States must adopt/implement the standard to maintain adequacy and compatibility. Certainly, the Commission retains the national legal mandate granted by Congress for the overall regulatory responsibility for the use and security of radioactive material; however, with the large number of Agreement States with the vast majority of radioactive material licensees nationwide, it seems the Agreement States must now be more deeply involved in the development of the "standards". Also, compatibility must now be more of a "mutual compatibility" than the previous "top down" compatibility. Who and how is the Commission's level of compatibility determined?</p> <p>The Policy Statement should be revised to acknowledge and recognize the Agreement States expanded role in the national regulatory arena.</p> | <p>Programs, but rather a modification was made in the Statements of Principles and Policy for Agreement State Programs. Under the section "Regulatory Development," the role of the Organization of Agreement States on regulatory issues was added.</p> |

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| 61 | 7 | AC | | <p>The subparagraph entitled "Discussion, I. Adequacy" includes descriptions of "five essential program elements" that an Agreement State program must contain (but are not required for compatibility) to provide a reasonable assurance of protection of public health and safety. The statement "The level of protection afforded by the program elements of the NRC's materials regulatory program is presumed to be that which is adequate to provide a reasonable assurance of protection of public health and safety." This basis statement includes words/phrases such as "presumed" and "reasonable assurance" that are not defined and are open to broad interpretation. How is "reasonable" assessed in terms of public health and safety protection?</p> <p>Also, please clarify the closing statement of subparagraph I. Adequacy. "The Commission will also consider, when appropriate, other program elements of an Agreement State that appear to affect the program's ability to provide reasonable assurance of public health and safety protection. Such considerations will occur only if concerns arise."</p> | <p>Reject: The words used in this section of the Policy Statement are there to allow a certain level of flexibility. No changes to the Policy Statement will be made.</p> <p>[These flexible terms are used to allow for differences in each regulatory program]</p> <p>These two sentences are written in a manner to again allow for flexibility. The intent of the Policy Statement is to be broad and not specific in order to allow for additional considerations over time. No changes to the Policy Statement will be made.</p> |
| 62 | 7 | AC | | <p>The subparagraph entitled "Discussion, I. Compatibility" provides descriptions of five program elements "...necessary to a larger nationwide interest in promoting an orderly pattern of regulation of radiation protection." Further, the elements are generally limited to areas of regulation involving standards</p> | <p>No response needed. Will respond to the additional comment on this topic later in the letter.</p> |

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| | | | | and actJVJtJes with significant transboundary implications. The Department is concerned with the phrase "significant transboundary implications" and has provided comments on this concern in the response to Item I, Topics for Additional Comment, found later in this letter. | |
| 63 | 7 | AC | | <p>The subparagraph entitled "Discussion, I. Compatibility. C. Category C" describes "Other Commission Program Elements", stating these "...are important for an Agreement State to have in order to avoid conflicts, duplications...on a nationwide basis." Please clarify "conflicts" and provide a definition of "conflicts" as used in this context.</p> <p>Also, the last sentence of subparagraph C states that Agreement States program elements may be more restrictive than the Commission's but should "not be so restrictive as to prohibit a licensed activity." It must be noted and acknowledged that State laws may be enacted that may be more restrictive and this action may be outside the control of the State Radiation Control Program.</p> | <p>Reject: The word conflict is defined in the associated Management Directive 5.9. The definition states: "The essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdictionor in the regulation of agreement material on a nationwide basis."</p> <p>No changes to the Policy Statement have been made.</p> |
| 64 | 7 | AS | | <p>. The subparagraph entitled "G. NRC Actions as a Result of These Findings" describes the options available to the NRC resulting from of the previously described adequacy and compatibility findings. The subparagraph states "The appropriate action will be determined on a case- by-</p> | <p>Reject: Not within the scope of the policy statement. Comment may be considered during the update of MD5.6, IMPEP and/or procedure level document.</p> |

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| | | | | <p>case basis by the MRB." (Management Review Board).</p> <p>It is understood that each MRB is comprised of different NRC management personnel and that membership varies between Agreement State reviews. How is consistency maintained between different MRBs for Agreement Statement review? Are established criteria available and used by each MRB to maintain a high level of consistency?</p> | |
| 65 | 7 | AS | G.3 Probation | <p>The subparagraph entitled "G.3 Probation" states the probationary period is normally one-year or less. It further states "If the State has not addressed the deficiencies, the NRC may extend the probationary period or institute suspension or termination proceedings."</p> <p>It must be noted that in some cases one-year may not be sufficient time to implement corrective action, particularly if the corrective action includes legislative action involving personnel and funding.</p> | <p>Accept in part: Thankyou for the opinion. While a year may not be sufficient time for a program to fully implement an action plan, it is expected that action is being taking to correct deficiencies. The policy statement was updated for the situation when the program has shown progress in addressing the deficiencies. In this case, the NRC may institute a period of Heightened Oversight or Monitoring.</p> |
| 66 | 7 | AC | Compat B Significant transboundary implication defintion | <p>The phrase "significant transboundary implication" is difficult to understand and the Policy Statement must be clearly written in a manner that is easily understood and subject to little, if any, interpretation.</p> | <p>Reject:</p> <p>See comment 13</p> |

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| | | | | <p>The proposed definition of "significant transboundary implication" includes the word "particular" for which an alternate phrase of "significant and direct" is being further proposed. Two specific comments are offered on the proposed revision definition:</p> <ul style="list-style-type: none"> • "Significant" is relative and can be equally vague and confusing as "particular", and • The word "significant" in the phrase "significant transboundary implication" should not be defined by using the same word in the definition. <p>The phrase "significant transboundary implication" must be replaced with a phrase using words that are easily and clearly understood that convey the <u>real basis</u> for the concept described by "significant transboundary implication", that being regulatory jurisdiction.</p> | |
| 67 | 7 | AC | Compat B Significant transboundary implication Examples | <p>Typically, examples should not be necessary in a policy statement. The policy should be sufficiently clear without examples. However, because of the uncertainty of the phrase "significant transboundary implication", (assuming the phrase is not totally revised), the Department recommends the Policy Statement be revised to include the following:</p> <p>When a new or revised standard, rule, or activity is proposed by the Commission</p> | <p>Reject: See comment 14</p> |

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| | | | | that includes significant transboundary issues, the Commission must specifically identify and justify the transboundary implications for inclusion in the proposed action. This identification/justification of the proposed action must be provided to the Agreement States early in the development process and prior to publication in the <i>Federal Register</i> for public comment. Further, any resultant action must be equally applied to the NRC and Agreement States. | |
| 68 | 7 | AC | Compat B Significant transboundary implication Goods services | "Movement of goods and services" most certainly must be included in "determining whether an issue has transboundary implications. However, it must be cautioned that certain activities, specifically services for which individual State regulatory agencies/Boards are the sole regulators of professional services (e.g., practice of medicine), are typically not transferrable/recognized by other States. | Reject: See comment 32 |
| 69 | 7 | AC | Compat B Significant transboundary implication Economic factor | Economic factors should not be a consideration in the compatibility determinations. The Department agrees with the NRC that health and safety should be the primary consideration. | Accept: See comment 15 |
| 70 | 7 | AC | Compat B alternate wording | The Department agrees the original language of the Policy Statement is satisfactory. Agreement States must be given the flexibility to manage the State Radiation Control Program within the jointly agreed upon and accepted Policy | Reject: See comment 13 |

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| | | | | Statement. The NRC Policy Statement must reflect this approach and the attitude of support for the Agreement States Program. | |
| 71 | 7 | AC | Summary and conclusions alternate wording | The Department agrees the original language of the Policy Statement is satisfactory. | Accept: The working group by 3-2 decision agreed with the majority of the comments requesting to return the language back to the original language from the 1997 policy statement. Changes to the Policy Statement have been made to change the language back to the original language as published in 1997. |
| 72 | 7 | Performance based compatibility | | Consistent with a previous comment provided in Topic 6, Agreement States must be given the flexibility to manage the Program and a performance-based approach for determining compatibility further supports greater flexibility. Certainly, there are other approaches to implement requirements than prescriptive requirements; however, issues such as future reciprocity with other jurisdictions must be thoroughly considered and evaluated. The Department supports this initiative by the NRC staff. | Comment to be considered under separate initiative. |
| 73 | 7 | Performance Metrics | | The Department supports this initiative by the NRC staff. However, Agreement | Comment to be considered under separate initiative. |

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| | | | | States must be actively involved with the development and implementation of the revised evaluation criteria for determining program adequacy. It must be stated that any resultant program revisions for determining adequacy must be equally applied to the NRC and Agreement States. | |
| 74 | 8 | AC | transboundary | The Board proposes the following definition of "significant transboundary implication": "One which crosses multiple regulatory jurisdictions and would have a consequential impact on public health and safety if not directly and equally adhered to." | Reject: See Comment 13 |
| 75 | 8 | AC | examples | The Board thinks that the examples of program elements with significant transboundary implications should be retained. Examples would include: dose limits, patient release criteria, transportation requirements, requirements on portable devices such as those used in industrial radiography, and training requirements. | Accept: See comment 14 |
| 76 | 8 | AC | Goods and services | The Board does not believe that the movement of goods and services across regulatory boundaries should be a major factor in determining whether a program element should be classified as a compatibility category B. The recent change in compatibility from B to C for certain GL rule sections is an example of why Agreement States need the flexibility to address health and safety issues for the movement of goods and services across regulatory boundaries. | Accept: See comment 32 |

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| 77 | 8 | AC | Economic facotrs | The Board does not believe that economic factors should be considered when assigning compatibility to a program element. We prefer to allow each Agreement State's legislative authority to set the economic impact limitations for their state. Economic impact is a moving target, and is affected by a myriad of laws and other factors that vary from state to state. | Accept: See comment 15 |
| 78 | 8 | AC | Original text |) The NRC has asked that specific comments be given regarding the text in the discussion of Compatibility B. The original text states "The Commission will limit this category to a small number of program elements that have significant transboundary implications." The alternative text states "The Commission will limit this category to program elements that have significant transboundary implications. The Commission expects that these will be limited in number." This alternative text was created on the premise that the original text somehow limited the Commission's authority. The Board believes that the original text from the 1997 document should be retained for a number of reasons. We agree that the original language in the 1997 version of the Policy Statement was not intended to dictate the Commission's authority but rather was to remind those staff proposing designations of compatibility B to the Commission for consideration that program elements of this designation should be few as opposed to many and should only involve significant transboundary implications. We believe the change | Reject: See comment 13 |

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| | | | | trivializes the intent on the part of the Commission to make serious consideration before assigning a category B to a program element, and deemphasizes the idea that Agreement States should be given flexibility when addressing program elements. The current text stresses the importance of not being cavalier in the decision making process. We also believe the text change adds no real content to the intent of the paragraph, and, in fact, takes attention away from the intent, which is to assure that Commission staff understands and considers the gravity and implications associated with assigning a compatibility level B to a program element. The new text implies that there are a small number of times that they need to make such considerations as opposed to always considering it and carefully deciding if it should be recommended to assign it as a B. | |
| 79 | 8 | AC | summary | The Commission is requesting comments on alternative versions of wording regarding the expectation on the number of regulatory requirements that Agreement States will be requested to adopt in an identical manner to maintain compatibility. The Board again believes the original text from the 1997 document should be retained. The original text places emphasis on the Commission's effort to minimize unnecessary burden on the Agreement States ability to accomplish the same goals as the NRC program elements. This allows and encourages flexibility to use the most efficacious means to meet the goals of a program element. | Accept: See comment 35 |

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| 80 | 8 | Performance based compatibility | | The Board supports giving the Agreement States as much flexibility as possible to regulate the possession and use of radioactive material in a manner that has proven most effective for them. The Board supports a performance-based approach in determining the compatibility of an Agreement State program. The Board would also recommend that if the NRC finds an Agreement State that is using a non-standard method that meets the compatibility objectives, it should publish these methods to the other Agreement States for review and possible adoption. | Comment to be considered under separate initiative. |
| 81 | 8 | IMPEP metrics | | The Board recommends that the current criteria for determining adequacy remain intact. A performance based approach to adequacy or “flexibility to be more stringent” does not mean that health and safety is compromised. There is a pervasive attitude that “flexibility” is needed because of shortcomings of Agreement States. This is demonstrated by the proposed new language that states the NRC should “consider the limitations of an Agreement State program and provide increased flexibility without compromising public health and safety”. This is an incorrect interpretation. The use of “flexibility” should not imply that the Agreement State is running a degraded program due to lack of sufficient resources. Additionally, the Board does not think that a holistic determination can be made to accurately reflect the compatibility and adequacy of a program. | Comment to be considered under separate initiative. |

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| 82 | 8 | General | | <p>Other comments regarding the IMPEP process</p> <p>a) The Commission should require an annual audit be performed by the Agreement State and NRC program which will be made available during the IMPEP.</p> <p>b) The Commission should consider creating a full-time IMPEP team leader to ensure consistency for the process and reports.</p> <p>c) The current IMPEP process does not provide an appeal process for the Agreement States. In other words, if a state disagrees with the findings of the MRB, there is no way to have an impartial third party review of the findings. The Commission should develop a process to give the States a right to an adjudicatory appeal of the MRB findings.</p> | <p>For comments (a) and (b), these comments to be considered under separate initiative.</p> <p>(C) The working group agrees that the current IMPEP process does not provide an appeal process for the Agreement States on most of NRC's determinations. Currently the Management Review Board (MRB), composed of senior NRC managers and an Agreement State Liaison, makes a determination on an Agreement State radiation program's adequacy and compatibility. The MRB's bases the determination on the IMPEP report and discussion with the Agreement State representatives participating in the MRB meeting. While the States are a State is given the draft IMPEP report to for review and comment before it is presented as the final IMPEP report to the MRB, there is no formal appeal process if the State disagrees with the MRB's determination or decisions</p> |

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| | | | | | <p>to put an Agreement State on Monitoring, Heightened Oversight, Probation, or, in some cases, Suspension or Termination. A State can informally request that the NRC reconsider the MRB decisions by sending a letter to the Commission or the NRC's Executive Director.</p> <p>The Commission would have to decide whether to establish a formal appeals process for MRB decisions other than those resulting from a hearing held under section 274j. of the Atomic Energy Act. Currently 274j allows the Commission, upon its own initiative, to terminate or suspend a State's agreement, provided the circumstances described in Section 274.j(2) [emergency suspension or termination] do not exist. The State must be provided with reasonable notice and opportunity for a hearing under section 274j. of the Atomic Energy Act. This hearing would most likely be governed by the NRC's rules of practice and procedure, 10 CFR Part 2,</p> |

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| | | | | | which include procedures to appeal a presiding officer's decisions in most cases. In the event the State or another party disagrees with the NRC's final determination, the decision could be appeals to a Federal Court of Appeals. In comparison, if the State requests termination or suspension of part or all of the agreement, a State may not request a hearing on the suspension or termination unless it disagreed with the NRC's proposed implementation of the suspension or termination. |
| 83 | 9 | AC | Purpose | In the second paragraph it is stated: For the purposes of this Policy Statement, "program element" means any (emphasis added) component or function of a radiation control regulatory program, including regulation and/or other legally binding requirements imposed on the regulated persons, which contributes to implementation of that program. The specification of any component it too broad in scope. The components need to be more clearly and/or narrowly described and must have a clear nexus to health, safety and security. | Reject: By stating that a program element is any component or function " of a radiation control regulatory program " sufficiently narrows the scope of what a program element can entail. No changes to the Policy Statement have been made. |
| 84 | 9 | AC | | In the last paragraph, the last sentence states' "The Commission will consider such | Reject: The Commission in its current practice is |

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| | | | | advice in its final decision.” This should be changed to the Commission will use it’s best efforts to arrive on a consensus with the Agreement States, as intended by the AEA. | meeting its obligations as stated under the AEA. No change to the Policy Statement has been made. |
| 85 | 9 | AC | | <p>1. Adequacy</p> <p>The H&S compatibility category is confusing and ill-defined. Many regulations contain the H&S category, and the Commission reviews and approves/disapproves a state's legally binding requirements in an identical manner as regulations designated as Categories A, B and C. This is likely to do with the fact that the only means to implement such H&S elements is via legally binding requirements and not by Agreement State program elements. The fact that the Commission has H&S in their regulations rather than in program elements supports this comment.</p> | <p>Reject:</p> <p>The working group determined that health and safety is a component of Adequacy. The discussion on program elements required in order to maintain public health and safety has been moved under the Adequacy Section of the policy statement.</p> |
| 86 | 9 | AC | | <p>Category D</p> <p>The discussion of this category needs revision, or more appropriately should be moved to a general overview of the categories and or included, in part, in Category C. Category D is simply those items that a state does not need to implement, period. The discussion regarding flexibility would be more appropriate in Category C, where the state can be more restrictive.</p> <p>The H&S category is not presented in this</p> | <p>Accept: Changes to Category D will be made and the additional text will be moved to another section of the Policy Statement.</p> <p>Reject: As stated in the Policy Statement category H&S is a matter of adequacy and therefore is not presented under the Section entitled</p> |

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| | | | | section, but should be. | Compatibility. No changes to the Policy Statement have been made. |
| 87 | 9 | AC | Compat B transboundary implication examples | <p>Section IV. Item 1.B. Compatibility B</p> <p>After 51 years of working experience for the Agreement State program, the Commission should easily be able to identify those regulatory areas which it has, and is presumed will continue to, designate as Compatibility B elements. The Commission has addressed health and safety for all these years and has identified Category B items in its recent implementation of 10 CFR 37. Therefore the Commission should include a listing of those specific areas for which it has determined have significant transboundary implications that warrant the use of Category B designations, and state why each program area identified has significant transboundary implications. If a clear listing is provided it may not be necessary to state that the Commission will limit the number of Category B elements. Also, we strongly disagree with the logic that the listing of examples could lead to misinterpretation by the Agreement States. Without a comprehensive list, the application of Category B would appear to be arbitrary.</p> | Reject: See comment 14 |
| 88 | 9 | AC | Compat B transboundary implication economic factors | The rulemaking process in New York State requires that the program take economic consideration (costs) to regulated parties in consideration and provide impact analysis | Reject: See comment 15 |

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| | | | | of such costs. The Commission should be aware of such state requirements when formulating new and revised regulations. | |
| 89 | 9 | Performanc based compatibility | | The Commission currently uses a process whereby regulations are reviewed by NRC Headquarters to determine a state's compatibility with Commission regulations and H&S item that are in NRC regulations. This is effectively performed outside of the IMPEP periodic review process, However the compatibility determination (indicator finding) is done in conjunction with review, and MRB meeting. Rather that attempt to use a performance based approach to the regulatory requirement component of compatibility, the Commission should consider moving such reviews outside of the IMPEP process. This may also reduce the amount of time and resources need to perform a IMPEP review. NRC has applied the H&S Category to certain regulatory requirements and considers these to be necessary for adequacy. Regulations should not be designated as H&S as the only mechanism the states have to implement such H&S elements is by legally binding requirements, not by Agreement State policies and procedures. Also, the Commission has consistently used Compatibility C designation for Agreement State program elements (other than regulations). Such items should be designated as Compatibility H&S. Compatibility A, B and C should apply only to regulations, and H&S should be limited to Agreement State | Comment to be considered under separate initiative. |

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| | | | | program elements other than regulations. This scheme would eliminate the current notion that there are compatibility items that are needed for adequacy. | |
| 90 | 10 | AC | Purpose | <p>We agree with the addition of the clarification that “public health and safety” includes physical protection of agreement material. Listing this statement early in the document limits the redundancy of repeating it in each section. We also agree with the use of the term “physical protection” instead of “security”.</p> <p>We do not understand why NRC sees the need to add the phrase, “Nor does this Policy Statement diminish or constrain the NRC’s authority under the AEA.” It is obvious that the requirements specified in the AEA are the Law and cannot be diminished or constrained by any statement of policy. This statement adds nothing to the policy, is redundant, and should be removed.</p> | <p>Accept: Thank you for your comment.</p> <p>Reject: This phrase is need for clarity since there is discussion in the Policy Statement on what the Commission should and should not do in determining items of Adequacy and Compatibility.</p> |
| 91 | 10 | AC | Background | <p>The language used to explain the requirements of AEA 274 follow the text of 274 closely except in the case of 274b, which uses the original word “discontinuing” instead to the proposed word “relinquishing”. We do not understand why the explanation of 274b differs from the actual AEA.</p> <p>We agree with and support the addition of the phrase, “In identifying those program elements for adequate and compatible</p> | <p>Accept: Based on the receipt of several comments requesting the word discontinue be used instead of relinquish. Changes to the Policy Statement have been made.</p> <p>Accept: No changes to the Policy Statement will be made.</p> |

Comment Resolution Table: SECY-12-0112, Policy Statements on Agreement State Programs
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| | | | | <p>programs, or and changes thereto, the NRC staff will seek the advise of the Agreement States. The Commission will consider such advice in its final decision.”</p> <p>Since this action has to be taken, it does not belong in the BACKGROUND section. We recommend that this phrase be added at the end of the DISCUSSION section.</p> | <p>Accept: Will move the last paragraph under the Background section into the Discussion section.</p> |
| 92 | 10 | AC | Discussion | <p>As mentioned above paragraph, move the phrase from the end of the BACKGROUND section to the end of the DISCUSSION section.</p> | <p>Accept: Will move the last paragraph under the Background section into the Discussion section.</p> |
| 93 | 10 | AC | Adequacy | <p>The last paragraph makes a subtle but very significant change. We recommend that the original text in the 1997 Policy Statement be used.</p> <p>The original text states:</p> <p>Specifically, Agreement States should adopt a limited number of legally binding requirements based on those of NRC because of their particular health and safety significance.</p> <p>The proposed text states:</p> <p>For those items that have significant health and safety implications, the NRC shall identify legally binding requirements that should be adopted by Agreement States. The NRC expects that there will be a limited number of such requirements.</p> | <p>Reject: The revised language continues to emphasize health and safety and links the legally binding requirements that Agreement State’s should adopt to those requirements that have a significant health and safety implication. The NRC is not limiting the amount of requirements that may need to be implemented but is merely noting that the expectation is that there will be a limited number of such requirements.</p> |

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| | | | | <p>The proposed text moves the attention from having these legally binding requirements because of each one's particular health and safety significance;</p> <ul style="list-style-type: none"> □ The proposed text also constrains NRC to have a limited number of these while the original text limits the number based on the particular significant health and safety events. □ The proposed text actually moves the focus from a particular health and safety statement and makes NRC consider limiting the numbers because they think they have already issued too many requirements. <u>This is a significant change.</u> <p>The original 1997 text provides NRC more flexibility in addressing particular health and safety events without limiting the number based on the number of "events" instead of requirements.</p> <p>Again, we recognize that this language shift is subtle but it is very significant and we recommend that the original text in the 1997 Policy Statement be used.</p> | |
| 94 | 10 | AC | Compatibility | <p>In the first paragraph, the sentence "Those program elements are generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications" is vague and capricious because the word "generally" may mean anything.</p> <p>We recommend that the word "generally" be</p> | <p>Reject: See comment #93.</p> <p>Further, no changes needed due to a re-write of the introductory paragraph on Compatibility.</p> |

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| | | | | changed to “should be” and the proposed text read “Those program elements should be limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications.” | |
| 95 | 10 | AC | Compat A&B | The proposed changes clarify the meaning. My experience with multiple IMPEP audits with different Agreement State regulations and writing regulations in Florida is that these categories do not need revisions. | Accept: No changes made to the Policy Statement. |
| 96 | 10 | AC | Compat C | <p>We recommend that in the last sentence delete the phrase “however, they should not be so restrictive as to prohibit a licensed activity.” We recommend that this sentence be changed to “Agreement State program elements may be more restrictive than Commission program elements.”</p> <p>If it is a requirement that an Agreement State wants to prohibit a licensed activity because of health and safety or physical protection reasons then they should be able to do so under Category C. Putting this disclaimer in Category C blurs the line between Category B and Category C. If NRC does not want a regulated activity prohibited by an Agreement State then it must meet Compatibility B criteria. Agreement States must have the flexibility to tailor their regulations based on their business processes and the states health and safety considerations under category C. Should this requirement be kept, then we would not meet the Category C designation for the generally licensed devices under rule</p> | Reject: Requiring a license is not prohibiting a licensed activity. In this context the word “prohibit” means the exclusion of all licensed activities. The use of additional constraints are not a prohibition of a use. No changes made to the Policy Statement. |

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| | | | | <p>31.5. We prohibit possessing all generally licensed devices (except tritium exit signs) unless the device is registered with the state and a per device fee is paid. We strongly feel that all generally licensed devices must be tracked and accounted for instead of a small subset of isotopes and activities listed in NRC's 10 CFR 31.5. We have registered all devices since early 1980 and we use the per device fee to inspect these facilities. Failure to register or pay the fee and we will prohibit this general licensed activity. In addition, some states require specific licensure for the devices listed in 31.5 due to their concerns for health, safety and security of the devices. Allowing this provision would automatically put them as not compatible because they take a more aggressive health and safety posture than NRC.</p> <p>Some Agreement States also issue regulations to require certain elements that are only an NRC policy requirement listed in NRC's NUREG 1556 guidance documents. For example, Florida has regulations NRC does not have regarding the use of fixed and portable devices and the possession and use of unsealed radioactive materials not listed in other regulations. (E.g. laboratories, R&D facilities, nuclear pharmacies, manufacturing and distribution facilities, consulting services, etc.) NRC licensing requirements are described in the NUREG 1556 guidance documents. Should an applicant not meet these requirements as</p> | |

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| | | | | <p>described in our regulations, then the licensed activity is prohibited. We would automatically not be compatible with NRC because we have regulations that prohibit a licensed activity that NRC does not even regulate.</p> <p>Do not blur the distinction between Category B and C. Agreements States must have the flexibility to be completely more restrictive than NRC under category C even if that includes prohibiting a licensed activity.</p> <p>Therefore we recommend that the statement “however, they should not be so restrictive as to prohibit a licensed activity” be removed.</p> | |
| 97 | 10 | AC | Summary | <p>We recommend that the last paragraph be returned to its original text as in the 1997 Policy Statement.</p> <p>As discussed in the ADEQUACY Section above, the change in the proposed text is subtle but produces a significant change. Since this is a summary and conclusion section of the material listed above, the reasons under ADEQUACY are the same as above.</p> <p>The proposed text moves the attention from having these legally binding requirements because of each one’s particular health and safety significance. The proposed text also constrains NRC to have a limited number of these while the original text limits the</p> | <p>Accept: The working group believes the language as published sufficiently addresses an initial concern. The published language included the original sentence, “The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility” but the new sentence that immediately followed—“The expectation is that these requirements will be</p> |

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| | | | | <p>number based on the particular significant health and safety events. The proposed text actually moves the focus from a particular health and safety statement and makes NRC consider limiting the numbers because they think they have already issued too many requirements</p> <p>We recommend using the original language which states: The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. At the same time, requirements in these compatibility categories will allow the Commission to ensure that an orderly pattern for the regulation of agreement material exists nationwide. The Commission believes that this approach achieves a proper balance between the need for Agreement State flexibility and the need for coordinated and compatible regulation of agreement material across the country</p> | <p>limited”— notes the expectation that these requirements will be limited and conveys the Commissions intention to keep the amount of these requirements limited, rather than inadvertently conveying a Commission commitment to do so. The remaining language discussing the orderly pattern for regulation and achieving a proper balance between flexibility and coordinated & compatible regulation has been retained in the revised draft policy statement.</p> |
| 98 | 10 | AC | transboundary | We recommend that the phase “significant and direct” be used instead of “particular”. | <p>Reject:</p> <p>See comment #13</p> |
| 99 | 10 | AC | examples | We recommend that examples should be kept in the policy statement. NRC should consider adding a disclaimer that these examples are not all inclusive to avoid misinterpretations. | <p>Accept:</p> <p>See comment 14</p> |
| 100 | 10 | AC | Original tex | As indicated previously, we recommend that the original text of the 1997 policy should be retained. If it is expanded or revised it | <p>Accept:</p> <p>See Comment 35</p> |

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| | | | | should be limited to saying “significant and direct” with examples and a disclaimer discussed in 1.a) and b) above. | |
| 101 | 10 | AC | Economic factors | <p>The NRC should absolutely not consider economic factors in making a compatibility B designation, or any compatibility designation. This is not part of the AEA agreement and States must have the flexibility to fund their programs according to their needs.</p> <p>Also, Florida, (as with any state) must go through their unique cost/impact economic analysis as part of the rule making process. Florida’s rulemaking economic consideration is required by statute and if a certain cost in a five year period is exceeded, the rule must be ratified by the legislature. If economic factors were part of the compatibility determination and it conflicted with Florida Statutes, we would not be compatible with NRC.</p> | <p>Accept:</p> <p>See comment 15</p> |
| 102 | 10 | AC | summary | <p>We strongly recommend retaining the original 1997 text “The Commission will limit this category to a small number of program elements (e.g., transportation regulations and sealed source and device registration certificates) that have significant transboundary implications.”</p> <p>Changing this wording deemphasizes that the agreement states should be given the flexibility when addressing the majority of program elements necessary for a compatible program and is contradictory to</p> | <p>Accept:</p> <p>See comment 35</p> |

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| | | | | <p>the closing paragraph above.</p> <p>NRC should not think that by keeping the original text in any way limits their authority to make necessary rules to protect public health and safety. This is clearly authorized by the AEA and any “statement of policy” cannot be considered to change the Commissions authority. We recommend that the original 1997 text be retained.</p> <p>“The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. At the same time, requirements in these compatibility categories will allow the Commission to ensure that an orderly pattern for the regulation of agreement materials exists nationwide. The Commission believes that this approach achieves a proper balance between the need for Agreement State flexibility and the need for a coordinated and compatible regulation of agreement material across the country.”</p> <p>The changes proposed will tend to make Agreement States become “NRC Clones” in how they run their programs. Due to different organizational structures, funding sources, business processes, rulemaking processes, and many other factors, the Agreement States must have the flexibility to run their programs dictated by their state governments and not NRC.</p> | |

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| 103 | 10 | Performance based compatibility | | <p>We agree with the concept of alternative methodologies to compatibility than relying on a 3-year time frame to adopt rules. Perhaps some thought can be put into changing the Management Directive to have “important” rules vs. minor rules. Currently they are weighted the same. Currently the Management Directive allows alternative approaches to rules such as license conditions and orders. This would also be consistent with NRC “Cumulative Effects of Regulations (CER)” (See ML 12223A162 and ML13135A267) where rules are prioritized.</p> <p>We recommend that the text on the Policy Statement on this issue remain the same as the 1997 text and appropriate changes be addressed in the Management Directives.</p> | Comment to be considered under separate initiative. |
| 104 | 10 | IMPEP metrics | | <p>The use of metrics system was tried by NRC prior to the IMPEP process where Agreement States has over 30 metrics to satisfy to be deemed Adequate and Compatible. These audits were also conducted every 18 months and later changed to two years. This process did not really reflect whether states were adequate and compatible. For example, one of the metrics was that a State should have 1.5 FTE per 100 Specific Licenses. This was a meaningless number because of states business processes and the fact that they regulated other radiation hazards (x-rays, linear accelerators and NARM). These audits required much more state resources to conduct and usually were performed by</p> | Comment to be considered under separate initiative. |

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| | | | | <p>one or two NRC people. Also, the metrics used were weighed in favor of large Agreement States to comply.</p> <p>The current IMPEP process looks for performance, not numbers and essentially is a “holistic” determination of an Agreement State’s Adequacy and Compatibility. NRC also should not try to combine adequacy and compatibility into a single finding because they are two completely different items.</p> <p>NRC should also take great care in adding metrics to the current IMPEP process. For example, the one metric currently used is the Status of Inspections. If a state has over 25% of new and priority 1, 2, 3 inspections overdue, they are unsatisfactory. For a small state with few of these licenses this is a small number (13 of 50) but a large state may miss the same number but be okay (20 of 200). Which is worse? The fact that you have over 20 past due inspections vs. 13 or that you are 10% in one case but 25% in the other.</p> <p>Any use of metrics in the IMPEP process needs to carefully considered and be part of the Management Directives not the policy statement.</p> | |
| 105 | 10 | AS | <u>E. Performance Evaluation</u> | The first paragraph of the proposed text states NRC will “ensure they will continue to be adequate and compatible after an agreement becomes effective.” | Accept with modification: The word “ensure” is used meets in the statutes. Changed to “...will periodically review to |

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| | | | | Recommend that the word “ensure” is deleted. NRC may make a finding whether a state is adequate and compatible but they cannot “ensure” it. | ensure...” |
| 106 | 10 | AS | <u>2. Probation</u> | <p>The last sentence does not provide the Commission the opportunity to place a State currently on probation to heightened oversight at the end of the probationary period. The only options are to continue probation, suspension or termination.</p> <p>A situation may arise where the State has addressed all of the “significant” deficiencies and would warrant being placed on heightened oversight instead of continuing the probationary period for minor deficiencies.</p> <p>Recommend that the text be changed to provide the Commission the option of going to heightened oversight from probation.</p> | Accept: The working group made a clarifying edit to indicate Monitoring and Heightened Oversight are options when a program on Probation shows progress in addressing deficiencies. |
| 107 | 11 | AS | | <p>The SWLLRWCC was established by Public Law 100-712 and, pursuant to the authority granted by P.L. 100-712 must do whatever is reasonably necessary to ensure that LLRW are safely disposed of and managed within the region. We are a major stakeholder in the Subject Policy Statement for the Agreement State Program, and yet the NRC seems set on a course of ignoring our concerns and shutting the door to further dialog.</p> <p>Meanwhile the existence of California's incompatibility issue continues- from early</p> | Reject: NRC agrees with the comment that the current process does not provide a Low Level Waste (LLW) Commission a way to formally appeal Subject Policy Statements decisions by NRC or Agreement States. However, LLW Commissions can informally request that the NRC reconsider these decisions by sending letters |

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| | | | | <p>2002 to the present (11 years) with the likelihood of reaching to at least the 2015 IMPEP year and beyond. For the record, our SWLLRWCC views the execution of the existing Subject Policy Statements as woefully lacking and unresponsive to genuine real world concerns for public safety. For us, years pass without anything coming out of the pipe.</p> <p>One recommended revision to the Subject Policy Statements is to give organizations like ours the right to formally appeal Subject Policy Statements decisions (or as in this case failure to make decisions) by NRC and Agreement States like CA.</p> | <p>to the Commission or the NRC's Executive Director. The Commission would have to decide whether to establish an "appeals" process for Low Level Waste (LLW) Commissions, which is outside the scope of the Statement of Principles and Policy for Agreement State Program.</p> <p>The NRC does periodically evaluate California's radiation protection program for Agreement State materials during the Integrated Materials Performance Evaluation Program (IMPEP) review. However, since the State does not have a LLW program it is not evaluated during the IMPEP review. The IMPEP review does evaluate the State's regulations and has found these provisions are not compatible with NRC's regulatory program. The NRC has requested the State revise the regulations so they are compatible with the NRC's national program or have the State's Attorney General provide an explanation on how the</p> |

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| | | | | | regulatory provisions are compatible with NRC's regulatory program. Currently, the State has not complied with the NRC's request and there are limitations on what actions the NRC can take to require an Agreement State to change their regulations or legislation. |
| 108 | 12 | AC & AS | | Put simply, the NRC has no legal authority to impose continuing compatibility requirements on Agreement States' programs, nor can it require these states to submit to periodic reviews of those aspects of their radiation control programs not directly related to the regulation of 11e.(2) materials as defined under the Atomic Energy Act (AEA). | Reject: The 1959 Federal-State Amendment added Section 274 to the Atomic Energy Act of 1954, as amended (AEA), 42 U.S.C. §§ 2011-2297h (2006), to establish a system for States to assume regulatory authority over certain types of radioactive materials that are otherwise subject to NRC regulatory authority. In AEA Section 274b., Congress authorized the Commission and States to enter into agreements where a State assumes, and the NRC relinquishes regulatory authority over specified radiological materials (byproduct, source and special nuclear material) to protect public health and safety. AEA Section 274d.(2) requires |

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| | | | | | <p>the NRC to enter into the agreement if the Commission finds that the State program is in accordance with the requirements of subsection o. <u>and in all other respects compatible with the Commission's program for regulation of such materials</u> and that the State program is adequate to protect the public health and safety with respect to materials covered by the proposed agreement. [Emphasis added.]</p> <p>Prior versions of 274d.(2) specifically required the Commission to make these finding before entering into a Section 274b. Agreement for States to assume regulatory authority over the specified byproduct, source and special nuclear material. Congress expanded the Commission's regulatory authority by authorizing the Commission to regulate uranium mill tailings in Uranium Mill Tailing Radiation Control Act (UMTRCA) as byproduct material. Congress revised 274d.(2) by inserting a</p> |

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| | | | | | <p>reference to the new subsection 274o. which required States to meet certain requirements to license and regulate uranium mill tailings. Other changes to the AEA, included adding Section 11e.(2) to the definition of byproduct material to specifically include “the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.” However, UMTRCA’s legislative history does not indicate that Congress intended to discontinue the Commission’s prior statutory authority and responsibilities regarding other types of AEA radioactive materials when it expanded the Commission’s authority to regulate uranium mill tailings.</p> <p>The 1959 Federal-State Amendment also enacted AEA Section 274j. which provided the Commission with the authority to terminate or suspend a Section 274b. Agreement</p> |

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| | | | | | <p>and reassert its regulatory authority in a State if the Commission finds the termination or suspension is required to protect public health and safety. This provision permitted the suspension or termination of Section 274b. Agreements only in their entirety, and required the Commission to provide notice and an opportunity for hearing before it could reassert its regulatory authority in a State upon its own initiative.</p> <p>The Uranium Mill Tailings Radiation Control Act of 1978 amended Section 274j. to permit the Commission to terminate or suspend part, instead of all, of a Section 274b. Agreement. By indicating that Section 274j. allowed termination or suspension of all or part of an agreement it is clear that Congress did not intend to limit the amendments to 274j. to 11e.(2) material. The amendment also broadened the grounds for such action to include noncompliance with one or more of the requirements of</p> |

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| | | | | | <p>AEA Section 274. In addition, Congress directed the Commission to periodically review such agreements and actions taken by the States under these agreements to ensure compliance with the provisions of AEA Section 274.</p> <p>This analysis is also relevant to the comment that Section 274j limits the Commission's authority to periodically review an Agreement State program to 11e.(2) material or include compatibility along with evaluating the Agreement State program adequacy to protect public health and safety. The NRC continues to maintain that the subsequent amendment of Section 274(j) in 1978 made the 1963 OGC opinion quoted in the commenter's letter as inoperative and that letter from 2002 adequately interprets the statutory provision:</p> <p>"Any question concerning the Commission's authority to conduct periodic reviews of Agreement State programs under Section</p> |

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| | | | | | <p>274(b) of the AEA was resolved by the 1978 amendment of Section 274(j) which specifically addressed the issue of the Commission's authority to periodically review the programs of Agreement States. Section 274(j), as amended, states in relevant part that "[t]he Commission shall periodically review such agreements and actions by the States under the agreements to insure compliance with the provisions of this section." The agreements referred to in the quoted sentence are the agreements entered into under Section 274(b). It is clear from the legislative history that the 1978 amendment addressed agreements as whole and not just agreements pertaining to 11e.(2) byproduct materials. (See H. R. Rep. No. 95-1480, pt. 2, at 44-45 (September 30, 1978).) Thus, the plain meaning of the amended language is that the Commission has the authority and responsibility to periodically review Agreement State programs</p> |

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| | | | | | <p>for the purpose of determining continued compatibility and adequacy. The results of such reviews may form the basis to terminate or suspend a Section 274(b) agreement in accordance with the other provisions in Section 274(j).” [Letter dated May 2, 2002 from Paul H. Lohaus, Director Office of State and Tribal Programs, to Clayton J. Bradt, Principal Radiophysicist, NYS Dept. of Labor.]</p> |
| 109 | 12 | AS | Statement of legislative intent | <p><i>“...the Commission has an obligation, pursuant to Section 274j. of the AEA, to review existing Agreement State programs periodically to ensure continued adequacy and compatibility. Section 274j. of the AEA provides that the NRC may terminate or suspend all or part of its agreement with a State if the Commission finds that such termination is necessary to protect public health and safety or that the State has not complied with the provisions of Section 274j.”</i></p> <p>These statements are false and are in direct conflict with a previous opinion of NRC Office of General Counsel:</p> <p><i>“Section 274 contains no requirement that compatibility be maintained by the States. Nor does the statute authorize the AEC to</i></p> | <p>Reject: See comment #108.</p> |

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| | | | | <i>terminate or suspend an agreement on any other ground other than that the action is required to protect the public health and safety. Although it is readily apparent that the turnover of responsibility will work satisfactorily only if Federal and State regulatory programs are compatible, the section reflects Congressional confidence that such compatibility will be achieved through cooperation. A unilateral power to require compatibility would appear to be inconsistent with both the nature of the program established and the underlying philosophy of the statute.</i> [Opinion of NRC General Counsel - May 9, 1963. Quoted from SECY 91-039, 2/12/91, page 8. Emphasis added] | |
| 110 | 12 | AS | Statement of legislative intent | The “standards” referred to in the House Report are the standards specific to the regulation of uranium mill tailing as specified in subsection 274(o) of AEA. The new subsection(o) was also added to Section 274 by UMTRCA. Furthermore, subsection (o) is the only place in all of Section 274 that addresses requirements directly to the States with the words “the State shall...” All other provision in section 274 are requirements specifically directed to the NRC and therefore not obligatory upon the States. A State can neither comply nor fail to comply with a requirement placed upon the NRC. | Reject: See comment #108. |
| 111 | 12 | AS | Statement of legislative | Clearly, it was the intent of congress that the new language added to 274(j) by UMTRCA applied only to that portion of a | Reject: See comment #108. |

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|--|-----------|------------------|---------------------------------|--|--|
| | | | intent | State's program related to 11e.(2) material, that is uranium mill tailings. On-going compatibility requirements of all other aspects of the Agreement States' programs is NOT authorized, either in this amendment or in any other subsections | |
| 112 | 12 | AS | Statement of legislative intent | With the authority neither to impose on-going compatibility requirements nor to review Agreement State programs against them, the <i>Policy Statement on Adequacy and Compatibility of Agreement State Programs</i> and the <i>Statement of Principles and Policy for the Agreement State Program</i> are completely undermined and must be withdrawn. Furthermore, the NRC's IMPEP program which reviews state programs must be revised <i>in toto</i> to reflect the absence of continuing compatibility requirements. | Reject: See comment #108. |
| Commentor provided suggested edits in red-line strikeout copies of both policies statements. | 13 | AS | full document | Suggest deleting "compatible" in under Purpose 2 nd paragraph, as how are interaction compatible | Accept with modification |
| | | | | Delete phrase "controlling the safe and secure use of agreement materials in paragraph 1 under 3. Adequate to Protecny Public Helath and Safety because programs don't control use but rather ensure licensees use properly | Accept: |
| | | | | Suggest deleting as movement of goods and services not necessarily trasnboundary " in 2 nd paragraph, 4. Compatbile in Areas of National Interest | Accept with modification: Removed interstate commerce, and movement of goods and provision of services. However, to further illustrate the "Compatible in Areas of National Interests," added |

Comment Resolution Table: SECY-12-0112, Policy Statements on Agreement State Programs
 The NRC published the proposed policy statements in the *Federal Register* on June 3, 2013 (78 FR 33122)

| Comment No. | Commentor | Policy Statement | Location in the Document | Comment | Resolution |
|-------------|-----------|------------------|--------------------------|-----------------------|---|
| | | | | | but are not limited to, aspects of licensing, inspection and enforcement, response to incidents and allegations” Each of these areas are required for adequacy but also have program elements for compatibility |
| | | | | Technical/style edits | Accepted with modificaitons and if appropriate. |

| Commentor # | ADAMS ML # | Commentor ID | Commentor Affiliation |
|-------------|-------------|-------------------------|--|
| 1 | ML13226A334 | Daniel B. Shrum | Energy Solutions |
| 2 | ML13226A542 | William P. Dornsife | Waste Control Specialist, LLC |
| 3 | ML13259A191 | Sean Chapel, President | Assocaition of Device Distributors and Manufacturers |
| 4 | ML13259A193 | Steven Harrison (VA) | Office of Radiological Health, Virginia Depratment of Health |
| 5 | ML13260A456 | James McNees (AL) | Alabama Departmenr of Public Health |
| 6 | ML13260A448 | Cheryl Rogers (WI) | Wisconsin Department of Health |
| 7 | ML13260A457 | Bernard Bevill (AR) | Arkansas Department of Health |
| 8 | ML13259A435 | Mealnie Rasmusson (OAS) | Organization of Agreement States |
| 9 | ML13259A434 | Stephen Gavitt (NY) | New York State Department of Health |
| 10 | ML13259A433 | Michael Stephens (FL) | Florida Departmenr of Health |
| 11 | ML13232A393 | Aubrey Godwin | Southwest Low-level Radiaiton Waste Commission Compact |
| 12 | ML13226A320 | Clayton J. Brandt | member of public |
| 13 | ML13260A559 | Michael Welling (VA) | Virginia Department of Health |