SUPPLEMENTAL REPORT OF THE JOINT NRC-AGREEMENT STATE WORKING GROUP FOR DEVELOPMENT OF IMPLEMENTING PROCEDURES FOR THE FINAL POLICY STATEMENT ON ADEQUACY AND COMPATIBILITY OF AGREEMENT STATE PROGRAMS

January 29, 1997

The Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs submitted a report on August 21, 1996 that was circulated for comment. This supplemental report summarizes the activities of the Working Group since submission of the August report, principally the analysis of comments received from the Agreement States and the public and the modification of the Policy Statement and implementing procedures in response to these comments. This supplemental report does not change the basic tenets and explanations discussed in the August report, but does describe specific changes to the Policy Statement and implementing procedures made in response to comments received. Therefore, this supplemental report and the August report should be considered in conjunction with each other.

Comments were received from members of the public, the Agreement States and NRC offices. Letters were received from the Organization of Agreement States, six individual Agreement State program directors, two industry organizations and one environmental group. Comments received addressed the following issue areas: (1) NRC-Agreement State cooperation, (2) compatibility, (3) continuation of compatibility following effective date of an agreement, (4) form of regulatory requirements, (5) Integrated Materials Performance Evaluation Program and (6) categorization scheme and categories assigned to specific rules. Attachment 1 contains the summaries of public and Agreement State comments and responses drafted by the Working Group. The Working Group also analyzed comments provided by NRC staff and this analysis is included as Attachment 2.

As a result of the comments, the Working Group made modifications to the draft final Policy Statement (Attachment 3) and revised the draft implementing procedures in Management Directive 5.9 (Attachment 4), Handbook 5.9 (Attachment 5) and OSP Internal Procedure B.7 (Revision 1) (Attachment 6).

The Policy Statement was modified to include additional language to emphasize the cooperative nature of the NRC-Agreement State relationship as indicated by the AEA, as well as to clarify what is meant by "adequacy" and "compatibility" and the distinction between these two fundamental concepts. Further, the Policy Statement was edited to conform to the legal position that NRC does not have the authority to stipulate to States the form that should be used to adopt legally binding requirements.

In addition, the language describing categories of program elements needed for compatible programs was edited and simplified. Rather than the six designations of 1, 2, 3.a, 3.a.S, 3.b and 3.b*, only four categories are used: A, B, C and D. Category A (formerly Component 1) encompasses basic radiation protection standards as defined in the Policy Statement, as well as related signs, symbols and definitions. Category B (formerly Component 2) are those program elements that have significant and direct transboundary implications, such as transportation regulations or sealed source and device registry sheets. Category C (formerly Components 3.a and 3.a.S) includes those program elements that would create conflicts, duplications or gaps in the nationwide regulation of agreement material if not adopted by an Agreement State. States should adopt the essential objectives of program elements in this category. Therefore, there is no need for a separate category that specifies that program elements adopted by the States should be "at least as stringent as" those adopted by NRC and program elements in the former 3.a.S component now are included in category C. Category D (formerly Components 3.b and 3.b*) identifies NRC program elements which do not affect compatibility.

With respect to rules formerly designated as 3.b*, the Working Group noted that the Policy

Statement in SECY 95-112 offers relatively detailed criteria for compatibility categories, but remains silent on the identification - either explicitly or by enumeration of specific criteria - of rules necessary for adequacy. Rather, for the program element "Legislative and Legal Authority," the Policy Statement indicates that "the State should have existing legally enforceable measures such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety in the regulation of agreement material in the State." The Working Group identified this lack of specificity as an inconsistency in the Policy Statement and concluded (1) that the Commission should be advised of this issue and (2) that certain NRC rules not necessary for compatibility nonetheless should be identified as necessary because of their particular health and safety significance. During its analysis of regulations in applicable parts of Title 10 of the Code of Federal Regulations, the Working Group developed criteria[1] to identify such rules that are identified in the charts in OSP Internal Procedure B.7 (Revision 1) by the designation "H&S" in the "Comment" column (formerly 3.b*). The Working Group concluded that the essential elements of rules so designated should be adopted by Agreement States for purposes of adequacy. By adopting the essential elements of these NRC rules, the State will afford a level of protection that is equivalent to that of the NRC program; however, the State also has the latitude to be more restrictive in those circumstances it deems necessary.

The Working Group identified several ways of reviewing Agreement States with respect to program elements identified as having particular health and safety (i.e. adequacy) significance (but that do not meet the compatibility criteria). These are listed below, along with possible advantages and disadvantages. The Working Group recommends that the Commission adopt the first option which the Working Group has reflected in the attached implementing procedures.

1. Each State should adopt the rules on the list identified by the Working Group as "H&S." The criteria developed and applied by the Working Group in development of this list will be applied to future NRC rulemaking actions that will be added to the list in accordance with the implementing procedures.

   Pros: Greater certainty and specificity: a prescribed list would make it easier to achieve consistent reviews of State programs.

   Protection of public health and safety is addressed.

   The procedures can be implemented without further staff resources to review existing NRC rules.

   Policy and procedures could be implemented immediately upon approval.

   Cons: The criteria may be difficult to apply in some cases since different scenarios may yield different results.

---

[1] To be designated as having particular health and safety significance, an NRC rule (1) must not be required for compatibility (i.e. it is assigned to category D) and (2) its absence from an Agreement State program could result directly (i.e. from two or fewer failures) in exposure to an individual in excess of the basic radiation protection standards identified in compatibility category A. The concept embodied by "2 or fewer" failures is that if the essential objective(s) of the rule were not adopted and implemented, then an event could occur that would not have occurred were the essential objectives adopted. This alone, or in conjunction with at most one other event, could result in excessive exposure to an individual.

Criteria differ from the approach used in the reactor area.

Determining reasonableness is subjective.

2. IMPEP approach. Under this approach, the NRC would not conduct a specific review of Agreement State regulatory requirements for the purpose of adequacy (i.e. their acceptability from a health and safety perspective). However, the NRC would, as in all cases, conduct a review of the State's regulatory requirements in order to ensure their consistency with NRC requirements designated as necessary for compatibility. Under IMPEP, however, the NRC would examine particular State requirements if a performance problem identified during a program review could be linked to a gap or problem in the State's requirements.

   Pros: States would have maximum flexibility.

   Consistent with performance-based review philosophy.

   The procedures can be implemented without further staff resources to review existing NRC rules.

   Cons: The review would be more subjective.

   May be difficult to implement consistently from State to State.

   It may be more difficult to achieve consistency among programs over time.

3. Specific review of NRC rules applicable to materials licensees by NRC staff to determine which are needed to provide adequate protection of public health and safety using different criteria (other than the Working Group's). While adequate protection designations are made for rules applicable to reactors, NRC has not employed a similar process for materials regulations.

   Pros: Clearly identifies those rules needed for adequate protection.

   IMPEP reviews will be easier and more consistent.

   Cons: Additional staff resources would be required to develop criteria and review existing NRC rules.

   Full implementation of policy would be delayed until review was completed.

4. A combination of 1. and 3 (The Working Group's recommendation would be implemented until staff completes a review of NRC rules against new criteria.)

   Pros: Would permit the immediate implementation of Policy Statement.

   Resource costs could be spread over several years.

   Cons: Decisions about earlier reviews of a state may be affected after final staff review of rules.

Changes in a rule's compatibility category or H&S designation from the Working Group designation to a new one based on different criteria would not be cost effective from either the State's or NRC's point of view.

With respect to comments concerning the categorization of specific NRC rules, the Working Group re-examined each rule categorization questioned in the comments and made changes as appropriate. Working Group members generally concurred on changes (or retention of the original designation) with the exception of 10 CFR 35.32, the medical quality management rule. In response to a recommendation from several Agreement States that the category of section 35.32 be changed to 3.b (Category D, not required for compatibility or health and safety), the Working group reconsidered the category for Section 35.32 and agreed not to change any paragraphs from their original 3.b* classification (not required for compatibility, but required because of health and safety significance, H&S). The Working Group also agreed to add paragraph (a)(5) of this section to this H&S category. Two Working Group members have provided individual views and written explanations of their positions on the categorization of this particular rule and these are included as Attachment 7 and Attachment 8.

In summary, in response to comments, some modifications were made to the final draft Policy Statement to clarify meanings and to simplify the descriptions of the compatibility categories. The Working Group continues to have concern about regulations that it identified as having particular health and safety significance. To this end, the Working Group recommends that such a set of NRC regulations be established and that Agreement States should adopt the essential objectives of these regulations for purposes of adequacy. The Working Group further recommends that those NRC rules identified as having particular health and safety significance by the Working Group using its criteria should constitute an initial set of such rules and that future rules that meet these criteria should be added to it.

ATTACHMENT 1

ANALYSIS OF AGREEMENT STATE AND PUBLIC COMMENTS

INTRODUCTION

The Working Group Report dated August 21, 1996 was distributed to Agreement States and panelists who participated in the November 15, 1994 public meeting on Adequacy and Compatibility and a notice of its availability was published in the Federal Register on September 19, 1996 (61 FR 49357).

Ten comment letters were received from six Agreement State program directors, the Organization of Agreement States, two industry organizations and one environmental group. Appendix A contains a list of the commenters.

The comments received were summarized and grouped by issue into the following six areas:

- NRC - Agreement State Cooperation
- Compatibility
- Continuing Compatibility
- Appropriate Form of Agreement State Regulatory Requirements
- Integrated Materials Performance Evaluation Program (IMPEP)
- Categorization Scheme and Rule Charts.

This analysis contains the summary of comments, the Working Group's responses and how they were disposed.

ISSUE: NRC - AGREEMENT STATE COOPERATION

COMMENT:

Several Agreement State commenters noted that the Policy Statement is prefaced by stating that it is guidance for the States and NRC, but that the implementing procedures seemed to require that States adopt certain items for compatibility purposes.

RESPONSE:

The Working Group was advised that the Commission does not use policy statements, in and of themselves, to impose requirements on licensees or Agreement States. Accordingly, absent implementing regulations, any requirements imposed on Agreement States by NRC stem directly from the Atomic Energy Act (AEA) itself and not from the Commission's policy statements. Section 274 requires that Agreement State programs be adequate to protect public health and safety and compatible with the Commission's program and that the Commission periodically "review such agreements and actions taken by the State under the agreements to ensure compliance with" the provisions of the Section 274. Given this framework, the Policy Statement on the Adequacy and Compatibility of Agreement State Programs, including the associated implementing procedures, contains the Commission's interpretation of the requirements in Section 274 and the approach that the Commission will take in fulfilling those statutory obligations.

DISPOSITION:

The Policy Statement and implementing procedures were conformed to reflect the above position.

COMMENT:

The Agreement States recommended that program elements that are to be "required" for compatibility purposes be determined jointly by the Commission and the Agreement States and that the Policy Statement be modified to reflect this, as well as emphasizing the special co-regulator relationship that exists between the NRC and the Agreement States.

RESPONSE:

The Working Group agrees that the special relationship between the NRC and the Agreement States that was established by Section 274 of the Atomic Energy Act should be reflected in the Policy Statement. This is not only to recognize this relationship, but also to recognize that this relationship necessitates the concept of compatibility. Section 274 states that the "Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible." With a large number of individual radiation protection programs nationwide, the Working Group recognizes that to maintain consistent nationwide regulation for certain activities some program elements must be consistent from jurisdiction to jurisdiction. These are the program elements identified as basic radiation protection standards, those with significant and direct transboundary implications, and those needed to ensure that conflicts and gaps in the nationwide pattern are avoided. Because the concept of compatibility is integral to this framework and because of the statutory direction

provided by Section 274, the Working Group recommends that those program elements necessary for compatibility be determined by the Commission following consideration of the advice of the Agreement States.

DISPOSITION:

The Policy Statement was revised to include language specifically addressing the issue of identification of program elements for adequacy and compatibility and to clarify the States' role in these processes. Implementing procedures in Handbook 5.9 and in OSP Internal Procedure B.7 (Revision 1), also were modified to clarify the States' role in these processes.

COMMENT:

Several Agreement States commented that it is generally not NRC's job to oversee implementation of federal statutes pertaining to other federal agencies and that NRC should leave this to the State and the appropriate federal agency. Another commenter questioned how NRC will handle the States' capabilities under the Clean Air Act.

RESPONSE:

As a general matter, the Working Group agrees with the comment. However, there are certain specific circumstances in which NRC has adopted regulations to ensure a coordinated approach to regulation (e.g., the constraint rule allowing the recission of Subpart I pertaining to the Clean Air Act) by two Federal agencies. The Working Group concluded that such regulations should be adopted by Agreement States to ensure the same type of coordinated approach by the State and a Federal agency. Such NRC regulations would be assigned to Compatibility Category C based on the rationale that they are needed to avoid gaps.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT:

One Agreement State commenter stated that the purpose of the Agreement State program should be to turn over all regulation of agreement materials eventually to the States and that the policy statement on adequacy and compatibility should be directed at fostering independence and minimizing intrusion into State programs.

RESPONSE:

The Working Group believes that determining the purpose of the Agreement State program is beyond its scope of work. However, the Working Group also notes that the Commission currently is addressing this issue with its Direction Setting Initiative (DSI) Number 4, NRC's Relationship with the Agreement States.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT:

The Agreement States recommended that the phrase "conflicts, duplications or gaps" not be used in the Policy Statement and that the term "essentially identical" be changed to "essentially equivalent."

RESPONSE:

The Working Group considered removing the phrase "conflicts, duplications or gaps" and decided that it should be retained since it appears in the legislative history of Section 274 of the AEA and provides some further explanation of situations that could cause a disruption of an orderly regulatory pattern. The Working Group also considered changing "essentially identical" to "essentially equivalent" and decided to retain the original language. This decision was based on the plain dictionary definitions of the words "identical" and "equivalent" and the opinion that in the cases of (1) radiation protection standards and related definitions, signs and symbols and (2) program elements with significant direct transboundary implications that identity, rather than equivalence, was the more appropriate term.

DISPOSITION:

No changes were made as a result of this comment.

ISSUE: COMPATIBILITY

COMMENTS:

Several commenters recommended that the program elements needed to prevent conflicts, duplications, gaps or other conditions that would jeopardize an orderly nationwide pattern of regulation of agreement materials (component 3.a; now designated Category C) should be included in component 2 (those with significant direct transboundary implications; now designated Category B) and be essentially identical to those of the Commission.

RESPONSE:

The Working Group believes that the Policy Statement reflects the position that States should have flexibility to implement programs as they determine necessary based on local conditions and competing priorities. Further, program elements necessary to prevent conflicts or gaps may not necessarily have significant and direct transboundary implications and would thus be inappropriately categorized according to the Policy Statement. The Working Group considered this recommendation and did not adopt it because it would limit the flexibility the States would have in implementing their programs.

DISPOSITION:

No changes were made as a result of this recommendation.

COMMENT:

This group of comments addresses the issue of whether State regulatory requirements should be identical to or more or less stringent than the corresponding NRC requirement.

One commenter recommended that State regulatory requirements must always be at least as stringent as, or more so, than NRC's including dose limits and other basic radiation protection standards.

Several commenters recommended that State regulatory requirements should always be the same as those of NRC and that adoption of more stringent requirements should require notification of NRC by the State and a mechanism to notify the regulated community. One commenter suggested requiring prior approval by NRC for more stringent State requirements and that such approval be granted based on public health and safety issues and another commenter viewed more stringent State requirements as a conflict.

One Agreement State commenter stated that a choice between essentially the same as NRC or more stringent than NRC was not an adequate range of choices for the States and further stated that basic radiation protection definitions, dose and discharge limits and related standards based on recommendations of national and international standard setting bodies should be identical with remaining requirements up to the discretion of the States. This commenter also noted the language of the [draft] policy statement that the "guiding concept over the years since the beginning of the Agreement State program in the area of compatibility has been to encourage uniformity to the maximum extent practicable while allowing flexibility, where possible, to accommodate local regulatory concerns" and took issue with it and questioned its basis.

The Agreement States agreed that certain requirements usually should be as stringent as those of NRC (those requirements with a particular health and safety significance or those involving specific statutory direction), but commented that State requirements should be as effective as the corresponding NRC requirements.

RESPONSE:

The Working Group recognizes that a certain degree of consistency is necessary for the regulation of agreement material on a nationwide basis. The Working Group also recognizes that Agreement State programs require flexibility to regulate effectively since States regulate more than just agreement material and they must address local needs and priorities while simultaneously providing a minimal framework of consistent requirements to ensure an orderly nationwide pattern of regulation without undue disruption of interstate activities.

The Working Group generally agreed with the philosophy outlined in the draft Policy Statement that the 3 categories (components) for compatibility achieved a reasonable balance between consistency in requirements on a nationwide basis and recognition of the need for Agreement State flexibility to meet local situations and competing regulatory responsibilities.

The conditions recommended by some commenters that (1) program elements should be essentially identical in all circumstances and (2) prior approval by NRC for any program element to be more stringent than NRC are not consistent with the Policy Statement and provide little latitude to the States in managing their programs. The Policy Statement indicates that an Agreement State's program is adequate to protect public health and safety if its level of protection is equivalent to, or greater than, the level provided by the NRC program. Thus, except for items in Category A or B, States have the latitude to be more stringent if necessary to meet local conditions. The recommendation that States always be allowed to be more stringent (including radiation protection standards) likewise was not adopted by the Working Group. The Working Group felt that the small number of requirements such as dose limits; definitions, signs,

labels, and terms needed for a common understanding of radiation protection principles; and those directly affecting transboundary activities should be the same from jurisdiction to jurisdiction. Other program elements needed to achieve compatible programs did not necessarily need to be identical nor did they always need to be as stringent as NRC. The latter point deals mostly with protection of public health and safety and is properly addressed by the IMPEP process.

DISPOSITION:

No changes were made as a result of these comments.

COMMENT:

A number of commenters requested definitions, explanations or clarifications of terms such as "essential objective," "essentially identical," "in the national interest," "disruption of regulation on a national basis" and "transboundary." Related to these comments were those of Agreement States that expressed concern that equivalent terms (e.g. stochastic and probabilistic) and definitions (e.g. reference man) which contained more up-to-date information would not be viewed as compatible.

RESPONSE:

The Working Group agrees with the comments that terms used in the Policy Statement and implementing procedures that are important to understand and implement the Policy should be explained and clarified.

The Working Group appreciates that in a highly technical field such as radiation protection, new information is constantly forthcoming and understands that a given regulatory agency may adopt more current information than others depending on timing of rulemaking and other factors. The Working Group believes that such differences should not be viewed as not compatible, but that equivalence of the differing provisions should be demonstrated to the satisfaction of both the State and the Commission.

DISPOSITION:

While the Policy Statement itself is not the appropriate vehicle to provide specific direction on these issues, the implementing procedures have been clarified to ensure that terms are defined or explained in a glossary to the Handbook and to explain that differing provisions may be compatible (i.e. there are acceptable substitutes for NRC language).

ISSUE: CONTINUING COMPATIBILITY

COMMENT

One Agreement State commenter expressed the view that Section 274 of the Atomic Energy Act does not require that compatibility be maintained after an agreement is effective. This position also was reflected in the recommended changes to the Policy Statement submitted by the Organization of Agreement States.

RESPONSE

The Working Group does not agree with this interpretation of the AEA. Both Sections 274d.(2) and 274g. indicate that the Commission must find a State program to be compatible with that of NRC's in order to enter into a Section 274b. agreement with the State. The Working Group agrees with the Commission's view that, pursuant to Section 274, an Agreement State's program should be compatible with NRC's program for the duration of the Agreement.

Subsection 274g. authorizes and directs the Commission to cooperate with the States in the formulation of radiation protection standards "to assure that the State and Commission programs for the protection against hazards of radiation will be coordinated and compatible." This provision demonstrates Congress' intention that the compatibility between the NRC's and Agreement State programs should be maintained on a continuing basis.

Section 274j.(1) calls on the Commission to suspend or terminate an Agreement State's program if "the State has not complied with one or more of the requirements" of the Section 274. The Commission believes that this phrase "one or more of the requirements," encompasses all requirements of Section 274, including the requirement for compatibility.

Finally, the lack of a continuing compatibility requirement would lead to some incongruous results. Under subsection 274d.(2), the Commission is authorized to enter into an agreement with a State if the Commission makes both requisite findings that the State program is compatible with the NRC's program adequate to protect public health and safety. Absent a continuing compatibility requirement, an Agreement State could divert from having a compatible program the day after any agreement is signed with NRC. This would render the Commission's initial compatibility finding required by Section 274d.(2) meaningless. Given these concerns, the Working Group agrees with the Commission's position that it does not believe that Congress intended such meaning for the compatibility requirement.

DISPOSITION:

No changes were made as a result of this comment.

ISSUE: APPROPRIATE FORM OF AGREEMENT STATE REGULATORY REQUIREMENTS

COMMENT:

Several commenters expressed concern regarding the proposal, as indicated in the Working Group report and in SECY-95-112, to require Agreement States to adopt certain regulatory provisions in the form of rules as opposed to other legally binding requirements. In addition, several commenters questioned the Working Group's proposal to require Agreement States to adopt rules for regulatory provisions applicable to four or more licensees.

RESPONSE:

The Working Group agrees that the relevant guidance in SECY-95-112 and the Working Group report deserves reconsideration and clarification. The way in which a particular state imposes regulatory requirements varies greatly from state to state due to the differing administrative procedures that exist across the country. Given this lack of consistency, the Working Group recommends that the Commission employ the following approach to address the Agreement

State's regulatory requirements. Agreement States should adopt those regulatory requirements that (1) are applicable to all licensees and (2) necessary for compatibility in Categories A, B, and C, in the form of a rule or other generic legally binding requirement. The use of generic requirements will help to avoid inconsistency and confusion that may result from the imposition of individual requirements on a case by case basis. Agreement States have the flexibility to impose such generic requirements in a manner consistent with a State's administrative laws. In addition, this approach does not interfere with the Agreement States' ability to impose additional requirements (such as individual license conditions) on specific licensees when appropriate.

The Working Group believes that requirements applicable to more than a few licensees should be adopted in the form of a generic requirement such as rule. However, as the appropriate approach to such issues will depend on the types of licensees involved, NRC should review a State's approach to such situations (i.e., requirements not applicable to all licensees) on a case by case basis and communicate any concerns it identifies to the State.

DISPOSITION:

The Policy Statement and implementing procedures were changed to conform to this position.

ISSUE: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP)

COMMENT:

One commenter questioned how a finding of 'compatible' or 'not compatible' will be made - whether "each condition must be met in full or . . . based on something akin to a 'preponderance of the evidence' standard" noting that the Policy Statement was unclear on this point.

RESPONSE:

Compatibility determinations will be made as part of IMPEP reviews of Agreement State programs that are done by joint NRC/Agreement State review teams using procedures that have been developed to provide NRC staff and the Agreement States guidance in this area. Generally, all program elements for compatibility need to be adopted. At the time of each review, any question about compatibility is discussed between the review team and State personnel and variations will be dealt with on a case-by-case basis.

DISPOSITION:

No changes were made in response to this comment.

ISSUE: CATEGORIZATION SCHEME AND RULE CHARTS

COMMENT:

Several commenters noted that the classification scheme was complex and difficult to use consistently.

RESPONSE:

The Working Group realized that compatibility categories outlined in the Policy Statement represented a paradigm shift from the current status. Under the current B.7 procedure, the four divisions for rules (1) are applicable only to regulations and (2) only describe the "degree of identicalness" that an Agreement State must adopt without giving a basis for why the particular regulation is required for compatibility. Under the proposed compatibility categories as outlined in the Policy Statement and classification scheme in the implementing procedures, the basis for determining which program elements (including regulations) are necessary for compatibility is given, as well as the degree of identicalness that should be adopted by the State. This may appear to be more complex, but in reality provides a simpler decision scheme because the basis for making the compatibility determination is factored into the process. The Working Group recommends that each compatibility category be assigned a letter to make it consistent with how the adequacy program elements are designated in the Policy Statement.

DISPOSITION:

The language of the Policy Statement section on compatibility was modified to make it simpler and easier to use. Implementing procedures likewise were modified to reflect these changes.

COMMENT:

One commenter noted that the same regulation can easily fit several categories.

RESPONSE:

The Working Group recognized that the same regulation may indeed fit more than one category based on the fact that many regulations are adopted for reasons of protection of public health and safety. However, the Working Group's task was to devise implementing procedures to identify those program elements necessary for compatibility as explained in the Policy Statement. Therefore, issues of health and safety notwithstanding, program elements (including regulations) were sorted based solely on the compatibility categories in a hierarchical fashion so that they were placed in the first category for which they met the criteria. For example, the definition of "becquerel" was placed in the category of radiation protection standards since it met these criteria first, although it could have been placed in the third category (requirements to avoid conflicts, duplications and gaps).

DISPOSITION:

No changes were made in response to this comment.

COMMENT:

One Agreement State commented that there is nothing in the policy to suggest what specific criteria NRC will use to decide which regulations it will require the states to adopt.

RESPONSE:

The Working Group noted that the commenter acknowledged that this comment was made on the draft published in the July 1, 1994 FR notice and resubmitted for the "final" Policy Statement

stating that there is very little difference between the two. The "final" Policy Statement contains the general categories for compatibility which should be adopted by the Agreement States. These are (1) radiation protection standards and closely related provisions, (2) regulatory requirements with significant and direct transboundary implications, and (3) regulatory requirements that are necessary to avoid conflicts, duplications and gaps between and among programs. The specific criteria for classifying program elements are found in the implementing procedures for the Policy Statement (Management Directive 5.9, Handbook 5.9 and OSP Internal Procedure B.7 (Revision 1)).

DISPOSITION:

No changes were necessary in response to this comment.

COMMENT:

An Agreement State commented that §20.2201(c) should be 3.b[1] (Category D) rather than 3.a (Category C) since it is hard to see why duplicate reporting or lack thereof would create a conflict or gap.

RESPONSE:

The Working Group agrees with the commenter that duplicate reporting in §20.2201(c), or lack thereof, would not create a conflict, duplication or gap.

DISPOSITION:

The compatibility category for §20.2201(c) was changed to 3.b (Category D) as recommended.

COMMENT:

An Agreement State commenter noted that the classification of 20.2205 as 3.b* (Category D, H&S) needs to be clearly explained since failure to provide an individual with a report of an actual exposure does not abrogate the licensee's duty to restrict additional exposures that could lead to a total in excess of the basic standards.

RESPONSE:

This regulation contains essential objectives that address individual health and safety issues involving the responsibility of regulators to insure that radiation doses with immediate potential health effects are accurately and sufficiently reported to those affected occupationally exposed workers or members of the public. This section does not meet the criteria for compatibility as set

---

[1] As the result of comments, the designations for the compatibility categories were changed from the number/letter combination format to letters. The correspondence between old and new designations is: 1 = A; 2 = B; 3.a & 3.a.S = C; 3.b = D; 3.b* = D with the identifier H&S to indicate particular health and safety significance. Since commenters used the old system, for the sake of clarity this analysis also will use the old terminology and reference the new category designations parenthetically.

forth in the policy statement and was thus classified initially as 3.b* (Category D, H&S). However, the identification of this requirement as one of health and safety significance allows States flexibility in the written composition while still retaining the essential health and safety objectives.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT:

An Agreement State commenter recommended that sections 30.35 and 40.36(a), (b) and (d) for financial assurance and recordkeeping for decommissioning should be 3.b (Category D) in its entirety, not 3.b* (Category D, H&S) while another Agreement State commenter recommended that sections 30.35(d) and 40.36(a), (b) and (d) for financial assurance and recordkeeping for decommissioning should be 3.a (Category C), not 3.b* (Category D, H&S) and the comment column should say "are" instead of "may be."

RESPONSE:

The Working Group considered the comment and continues to conclude that this requirement meets the criteria of a provision with health and safety significance and should remain as 3.b* (Category D, H&S), indicating it is not required for compatibility purposes but should be identified as one with health and safety significance. The Working Group agrees with the language change in the "Comment" column.

DISPOSITION:

The compatibility category was not changed as a result of this comment. The recommended wording change for the "Comment" column was adopted.

COMMENT:

Several Agreement State commenters recommended that sections 30.36(h) and 40.42(h) specifying a time frame for decommissioning a site or requesting license termination should be 3.b (Category D), rather than 3.b* (Category D, H&S).

RESPONSE: The Working Group considered the comment and continues to conclude that this requirement meets the criteria of a provision with health and safety significance and should remain as 3.b* (Category D, H&S), indicating it is not required for compatibility purposes but should be identified as one with health and safety significance.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT:

Several Agreement State commenters recommended that for section 30.41, in the "Comment" column, the phrase "for the implementation of a coherent national program" should be replaced with "to prevent unnecessary restriction of interstate commerce."

RESPONSE:

The Working Group agrees with the proposed language change to clarify that there is not a single national program. However, since activities other than commercial ones may be undertaken, the Working Group suggests the more general language "to provide coherent regulation of agreement material on a nationwide basis."

DISPOSITION: The language change was incorporated.

COMMENT:

Several Agreement States recommended that for section 35.32, medical quality management programs, all paragraphs should be 3.b (Category D), rather than some being 3.b* (Category D, H&S).

RESPONSE:

The Working Group re-examined Section 35.32 and concluded that the provisions of this section meet none of the objective criteria to designate it as a 1 (Category A), 2 (Category B) or 3.a or 3.a.S (Category C). Upon further examination, the Working Group continued to conclude that paragraphs (a)(1) through (4), (b) and (c) met the criteria to be designated 3.b* (Category D, H&S). In addition, the Working Group concluded that paragraph (a)(5) also met the health and safety criteria, but that paragraphs (d), (e) and (f) did not.

DISPOSITION:

No changes were made to existing compatibility categories with the exception of paragraph (a)(5) that was redesignated 3.b* (Category D, H&S) from 3.b (Category D).

COMMENT:

An Agreement State commenter noted that for section 36.1, the 3.a classification (Category C) needs to be explained.

RESPONSE:

The Working group concluded the irradiator types and quantitative values specified in paragraph (b) and irradiator types specified in paragraph (c) were essential objectives of the requirements in section 36.1, and therefore, should be adopted by Agreement States to avoid potential conflicts in the nationwide regulation of agreement material.

DISPOSITION:

An explanatory comment was included in the B.7 chart that was revised to state more clearly the reason for the 3.a (Category C) designation.

COMMENT:

An Agreement State commenter recommended that section 40.42(c), (d), (e), (g), (h), (l), (j) and (k) decommissioning or requesting license termination should be 3.b (Category D), not 3.b* (Category D, H&S).

RESPONSE:

The Working Group has reconsidered the compatibility categories for these sections and concludes that 40.42(c), (d), (e), (h), (j) and (k) (that appeared twice) should remain as 3.b* (Category D, H&S). The Working Group agrees that section 40.42(g) and (l) do not meet the criteria for either 3.a (Category C) or for identification as having particular health and safety significance.

DISPOSITION: The compatibility designations for paragraphs 40.42(g) and (l) were changed to 3.b (Category D).

APPENDIX A

List of Commenters

Letter dated October 26, 1996 from Judith H. Johnsrud, Ph.D., Director, Environmental Coalition on Nuclear Power, 433 Orlando Avenue, State College, PA 16803.

Letter dated October 30, 1996 from Mark A. Doruff, C.H.P., Council on Radionuclides and Radiopharmaceuticals, Inc., 3911 Campolindo Drive, Moraga, CA 94556-1551.

Letter dated October 31, 1996 from John L. Erickson, Acting Division Director, Division of Radiation Protection, Washington Department of Health, Olympia, WA 98504-7827.

Letter dated October 31, 1996 from Thomas W. Ortciger, Director, Illinois Department of Nuclear Safety, 1035 Outer Park Drive, Springfield, IL 62704.

Letter dated October 31, 1996 from Richard A. Ratliff, P.E., Chief, Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin TX 78756-3189.

Letter dated November 6, 1996 from Felix M. Killar, Jr., Director, Material Licensees and Nuclear Insurance, Nuclear Energy Institute, 1776 I Street NW, Washington, DC 20006-3708.

Letter dated November 7, 1996 from Michael H. Mobley, Director, Division of Radiological Health, Tennessee Department of Environment and Conservation, 401 Church Street, Nashville, TN 37243-1532.

Letter dated October 3, 1996 from Robert M. Quillin, Chair, Organization of Agreement States, c/o Radiation Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, CO 80222-1530.

Letter dated November 7, 1996 from Thomas E. Hill, Manager, Radioactive Materials Program, Georgia Department of Natural Resources, 4244 International Parkway - Suite 114, Atlanta, GA 30354.

Letter dated November 12, 1996 from Rita Aldrich, Principal Radiophysicist, New York State Department of Labor, Radiological Health Unit, Albany, NY 12240.

ATTACHMENT 2

ANALYSIS OF NRC COMMENTS

Addendum

Subsequent to the submission of the January 29, 1997, "Supplemental Report of the Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," the following revisions were made to the Analysis of NRC Comments.

General Comments:

COMMENT 4:

In their current format, the tables were difficult to review. In places where the regulatory citation or definition was the same as that for another 10 CFR Part, under the heading "Classification Assigned," the citation for the other 10 CFR Part is listed but the numerical classification code was not included. In those cases, the table should be clear that the code assigned to the other section applies.

RESPONSE:

The Working Group agreed with this comment and revised the format of the charts.

DISPOSITION:

The tables were revised to indicate the classification from another 10 CFR Part in brackets, "[]."

Specific Comments:

COMMENT 8:

In Subpart K of 10 CFR Part 20, "Waste Disposal," the general requirements in 20.2001 are classified as category 3.a., but the requirements addressing specific disposal are classified as 3.b. We believe category 3.a., or 3.b* is the appropriate category.
~~The compatibility category for sewer disposal provisions needs to be re-examined.~~

RESPONSE:

The Working Group reconsidered all provisions related to ~~sewer disposal~~ specific disposal techniques in 10 CFR 20.2003~~2~~ through 20.2005, applying criteria based on the Policy Statement. The Working Group concluded after re-examination that its initial categorizations were appropriate.

COMMENT 40:

Many definitions in 10 CFR Part 61 previously classified as Division 1 are now category 3.b. (D), including such terms as "explosive material," "pyrophoric liquid," and "stability." We believe the terms should be at least a 3.a. (C). In addition, 61.23, 61.42, 61.43, and 61.61 are 3.b.; we believe these provisions should be retained in Agreement State Programs.

RESPONSE:

The Working Group reconsidered the categorization of the definitions described in the comment above, applying criteria based on the Policy Statement. The Working Group concluded after re-examination that its initial categorizations were appropriate. The Working Group also reconsidered the categorization of the provisions in 10 CFR 61.23, 61.42, 61.43 and 61.61. The Working Group concluded that revisions should be made to 10 CFR 61.23, 61.42, and 61.43 (see Disposition below). In particular, portions of 61.23 and 61.43 were identified as meeting the criteria for having particular health and safety significance. The Working Group concluded that 61.61 did not meet either the compatibility criteria or the criteria for particular health and safety significance.

DISPOSITION:

10 CFR 61.42 was designated as H&S, and a comment was added for 61.43 to note that it is already covered by Part 20 provisions. Other changes addressed 61.23; "H&S" was assigned to paragraphs (a) through (h), NRC assigned to paragraphs (i) and (j) and "D" was assigned to paragraphs k and l.

COMMENT 41:

The decommissioning timeliness and financial assurance provisions are not treated consistently in the various 10 CFR Parts. The commenter specifically cited the differences between the classification of 10 CFR 70.25 and 70.38 and similar provisions in 10 CFR Parts 30 and 40.

RESPONSE:

The Working Group reconsidered all provisions related to the comment above. The Working Group concluded after re-examination that 70.25 and 70.38 should be changed to comport with similar provisions in Parts 30 and 40.

DISPOSITION:

The classifications for 70.25 were changed to D (formerly 3.b) with paragraphs (a), (b), and (d) also assigned "H&S;" 70.38 was changed to D with paragraphs (c), (d), (e), (g), (h) and (k) also assigned as "H&S."

The above changes have been incorporated into the comment analysis text, which begins on the next page.

I. GENERAL COMMENTS:

COMMENT 1:

The classification scheme was found to be cumbersome and difficult to apply consistently.

RESPONSE:

The Working Group realized that compatibility categories outlined in the Policy Statement represented a paradigm shift from the current status. Under the current B.7 procedure, the four divisions for rules (1) are applicable only to regulations and (2) only describe the "degree of identicalness" that an Agreement State must adopt without giving a basis for why the particular regulation is required for compatibility. Under the proposed compatibility categories as outlined in the Policy Statement and classification scheme in the implementing procedures, the basis for determining which program elements (including regulations) are necessary for compatibility is given, as well as the degree of identicalness that should be adopted by the States. This may appear to be more complex, but in reality provides a simpler decision scheme because the basis for making the compatibility determination is factored into the process. The Working Group recommends that each compatibility category be assigned a letter to make it consistent with how the adequacy program elements are designated in the Policy Statement.

DISPOSITION:

The language of the Policy Statement section on compatibility was modified to make it simpler and easier to use. Implementing procedures likewise were modified to reflect these changes.

COMMENT 2:

A major difference between the current classification system and the proposed classification system is that the new classification system the new classification system does not establish requirements for the Agreement States to meet in order to be considered compatible. Absent specific requirements, it would mean that an Agreement State would never be found 'not compatible' since NRC did not define those regulations that must be adopted by the States.

RESPONSE:

The Commission does not use policy statements, in and of themselves, to impose requirements on licensees or Agreement States. Accordingly, absent implementing regulations, any requirements imposed on Agreement States by NRC stem directly from the Atomic Energy Act (AEA) itself and not from the Commission's policy statements. Section 274 requires that Agreement State programs be adequate to protect public health and safety and compatible with the Commission's program and that the Commission periodically "review such agreements and actions taken by the State under the agreements to ensure compliance with" the provisions of the Section 274. Given this framework, the Policy Statement on the Adequacy and Compatibility of Agreement State Programs,

including the associated implementing procedures, contains the Commission's interpretation of the requirements in Section 274 and the approach that the Commission will take in fulfilling those statutory obligations.

DISPOSITION:

The Policy Statement and implementing procedures were conformed to reflect the above position.

COMMENT 3:

Having a category of program elements that is not required for compatibility, but is required for health and safety, begs the question - was health and safety considered in any of the other classifications and if it is not health and safety related then why is it a compatibility requirement.

RESPONSE:

The Policy Statement makes a clear distinction between the fundamental concepts of "adequacy" being related to protection of public health and safety and "compatibility" being the core requirements for consistent nationwide regulation of agreement materials. The Working Group recognizes that, with the exception of a few administrative matters, all NRC regulations have an underlying health and safety purpose. However, the compatibility category identifies those NRC regulations that an Agreement State should adopt because of their impacts on regulation in other jurisdictions and on the regulation of agreement material on a nationwide basis. As such, it was the purpose of the Working Group to identify those NRC program elements (which includes regulations) that are necessary to maintain compatible programs between NRC and the States. In performing this task, the Group noted that certain NRC regulations were of a particular health and safety significance although they did not meet the compatibility criteria set forth in the Policy Statement. Further, the Working Group concluded that requirements for compatibility focus primarily on the effects of State action or inaction on other jurisdictions. As such, the concept of compatibility does not directly address matters of health and safety within a particular Agreement State. The Working Group, however, also recognized that certain program elements (including regulations) while important for health and safety reasons within the State (e.g. basic radiation protection standards), should be consistent nationwide primarily for the purpose of compatibility.

DISPOSITION:

This issue is addressed in changes to the Policy Statement and implementing procedures.

COMMENT 4:

In their current format, the tables were difficult to review. In places where the regulatory citation or definition was the same as that for another 10 CFR Part, under the heading "'Classification Assigned," the citation for the other 10 CFR Part is listed but the numerical classification code was not included. In those cases, the table should be clear that the

code assigned to the other section applies.

RESPONSE:

The Working Group agreed with this comment and revised the format of the charts.

DISPOSITION:

The tables were revised to indicate the classification from another 10 CFR Part in brackets, "[]."

II. SPECIFIC COMMENTS

COMMENT 1:

Sections 19.14, 19.15, 19.16, 19.18 and 19.20 should be 3.b* rather than 3.b since these sections were designed to provide workers with protected means of bringing their concerns to the agency and for the agency to maximize its means of obtaining information about the licensee's operations. A 3.b classification may lead to reducing the effectiveness of these means and, therefore, may be a safety concern.

RESPONSE:

The Working Group re-examined these sections using objective criteria based on the Policy Statement and concluded that they did not meet the criteria for health and safety. However, since these provisions (with the exception of Section 19.20) were adopted by NRC to ensure a coordinated approach to worker protection by OSHA and NRC, the Working Group concluded that Agreement States should adopt the essential objectives of these sections to ensure the same coordinated approach by the Agreement States and OSHA.

DISPOSITION:

Sections 19.14 through 19.19 were recategorized as 3.a (Category C).

COMMENT 2:

Section 20.1001(b) contains an important policy provision and should be classified as a "1."

RESPONSE:

The Working Group considered the comment and concluded that this section does not meet the criteria for Component 1 (Category A) since it is not a radiation protection standard as defined by the Policy Statement.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 3:

The definition of "declared pregnant woman" in Section 20.1003 should be classified as a "3.a" since it is intended to ensure that pregnant women who do not want to have their [radiation] duties curtailed for purposes of reducing their doses were not forced into that position.

RESPONSE:

The Working Group agrees with the commenter with respect to the intent of this provision. However, the Working Group initially designated this as Component 1 (Category A) since it is a definition that is necessary to understand basic radiation protection principles - evaluation of dose to an occupationally exposed individual. As such, the Working Group concluded that anything other than an essentially identical definition was not appropriate and that this definition should not be designated as Component 3.a (Category C).

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 4:

In Section 20.1003, the definition of "dosimetry processor" should be classified as a "2" if NVLAP accreditation is to be required.

RESPONSE:

The Working Group reconsidered this definition and concluded that it does not have significant and direct transboundary implications and, therefore, does not meet the objective criteria for Component 2 (Category B) as set forth in the Policy Statement.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 5:

In Section 20.1003, the definition of "entrance or access points" should be classified as a "1" since this definition was developed to avoid misunderstandings (essential definition) in connection with entry points that are not doors or windows, as well as certain partial body irradiation situations.

RESPONSE:

The Working Group considered the comment and concluded that this definition was not one that was essential to understand basic radiation protection principles. However, the Working Group did conclude that this definition was important to avoid conflicts and gaps between jurisdictions and Component 3.a (Catagory C) allows a State to include additional information in the definition. For example, a State may consider that an "access point" would include any access to a radiation source that would allow significant extremity exposure (e.g. the gap distance for a materials gauge).

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 6:

In Section 20.1003, the definition of "individual monitoring devices" should be classified as a "1."

RESPONSE:

The Working Group considered the comment and continued to conclude that this definition did not meet the criteria for a basic radiation protection standard or related definition. The designation of Component 3.a (Category C) retains the essential objective of the provision, but allows the States flexibility to add additional examples of acceptable monitoring devices.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 7:

In Section 20.1003, the definition of "respiratory protection device" should be classified as a "1" if Appendix A to Part 20 is to be retained in State programs. This is an essential term.

RESPONSE:

The Working Group considered the comment and continued to conclude that this definition did not meet the criteria for a basic radiation protection standard as defined in the Policy Statement. The designation of Component 3.a (Category C) retains the essential objective of the provision, but allows the States flexibility to add additional examples of acceptable respiratory protection devices.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 8:

In Subpart K of 10 CFR Part 20, "Waste Disposal," the general requirements in 20.2001 are classified as category 3.a., but the requirements addressing specific disposal are classified as 3.b. We believe category 3.a., or 3.b* is the appropriate category.

RESPONSE:

The Working Group reconsidered all provisions related to specific disposal techniques in 10 CFR 20.2002 through 20.2005, applying criteria based on the Policy Statement. The Working Group concluded after re-examination that its initial categorizations were appropriate.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 9:

Most of the requirements in Subpart L to Part 20 should be classified as "3.b*" since the records required by this subpart provide an important means of monitoring the safety level of a licensee's program and the degree of control the licensee has over its operations.

RESPONSE:

This comment was considered by the Working Group and concluded that most of the requirements in Subpart L did not meet the objective criteria used to classify them as 3.b* (Category D, H&S). The Working Group did retain its initial categorization of certain recordkeeping requirements as Component 3.a (Category C) that it deemed important to avoid conflicts and gaps between jurisdictions.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 10:

Appendix A to Part 20 should be classified as a "1" since the wording of the material in this appendix was selected to be compatible with national and international standards. Changes in wording may lead to subtle, but important, changes in meaning that may in turn affect safety.

RESPONSE:

The Working Group concluded that Component 3.a (Category C) is appropriate since it ensures that Agreement States will adopt the essential objectives of Appendix A to Part 20. State regulators are allowed flexibility to include additional guidance (or conservatism) as may be needed in their particular jurisdictions. This Appendix cannot be Component 1 (Category A) since it is not a radiation protection standard as defined in the Policy Statement.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 11:

Section 31.5 should be classified as a "2" since without some consistency in requirements for users in NRC and Agreement States compliance with the regulations will decrease.

RESPONSE:

The Working Group concluded that Agreement States should have the flexibility to regulate the devices addressed by section 31.5 more closely than is practicable under a general license. If an Agreement State does not choose to adopt a regulation equivalent to section 31.5, it must issue specific licenses in order to authorize licensees to possess and use these devices. Since specific licensees are regulated more stringently than general licensees, consistency in the regulation of these devices on a nationwide basis will be maintained, and compliance with the applicable regulations will remain the same or increase.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 12:

Section 31.6 should be classified as a "2" since most of the vendors and service companies use this general license to conduct work in other jurisdictions without the need to file pursuant to 10 CFR 150.20.

RESPONSE:

The Working Group concluded that the requirement for an out of jurisdiction licensee to file a report of proposed activity under reciprocity is an administrative matter, and does not carry significant and direct transboundary implications in and of itself. Therefore, this provision does not meet the criteria for Component 2 (Category B).

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 13:

Section 31.8 should be classified as a "2" based on the distribution of the product on a nationwide basis.

RESPONSE:

The Working Group concluded that Agreement States should have the flexibility to regulate the sources addressed by section 31.8 more closely than is practicable under a general license. If an Agreement State does not choose to adopt a regulation equivalent to section 31.8, it must issue specific licenses in order to authorize licensees to possess and use these sources. Since specific licensees are regulated more stringently than general licensees, consistent regulation of these devices on a nationwide basis will be maintained.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 14:

The comment for Section 32.2 indicates that the term "dose commitment" is superseded by Part 20. This is not true; many of the safety criteria in Part 32 continue to use this term and the regulation is based on this term.

RESPONSE:

The essential objective of both definitions, "dose commitment" in section 32.2 and "committed dose equivalent" in section 20.1003, is to account for the radiation exposure extended over time resulting from internally deposited radioactive materials. Both definitions require consideration of the total dose to the organs or tissues in which the radioactive materials are deposited, during a 50 year period following the intake. Thus, the definitions are equivalent, however, the part 20 definition is stated in more current radiation protection terminology. Agreement States should adopt the part 20 definition for purposes of compatibility, and should simultaneously amend their regulations and/or other legally binding requirements to replace the term "dose commitment" with the term "committed dose equivalent" at each occurrence.

DISPOSITION:

The language for the comment for Section 32.2 has been clarified to reflect the response to this concern.

COMMENT 15:

The term "lot tolerance percent defective" should be classified as a "3.b" since it typically is not used by Agreement States.

RESPONSE:

The Working Group agrees that most Agreement States do not use the term. However, it is used in section 32.110, an equivalent of which should be adopted by an Agreement State that issues licenses under requirements equivalent to sections 32.53, or 32.61. Since these sections are assigned to Component 2 (Category B), it is appropriate to assign the definition to the same category.

DISPOSITION:

The definition of "lot tolerance percent defective" has been designated as Component 2 (Category B).

COMMENT 16:

Section 32.24 is assigned the category "NRC" meaning that Agreement States should not adopt an equivalent regulation. However, section 32.51 that is assigned to Component 2 (Category B) references section 32.24 as licensing criteria. Thus, an Agreement State adopting a regulation equivalent to section 32.51 should adopt a requirement equivalent to section 32.24. Section 32.24 should be assigned to Component 2 (Category B) for Agreement States that adopt requirements equivalent to 32.51, and an appropriate comment added.

RESPONSE:

The Working Group agrees with the comment.

DISPOSITION:

The compatibility category for section 32.24 has been changed to 2 (Category B) and a comment has been added that cross-references section 32.51.

COMMENT 17:

Section 32.11(b) and 32.13 should be classified as a "2" because of the transboundary implications.

RESPONSE:

The Working Group concluded that the transboundary implications did not rise to the significance required for Component 2 (Category B). In the absence of any description of

specific transboundary implications that the commenter believes are direct and have such significance, the Working Group concluded that the category should not be changed.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 18:

Why are Sections 32.72 and 32.74 classified as "2" when the uses defined in Part 35 are not a matter of compatibility and the Part 35 regulations contain limitations that distribution activity must address.

RESPONSE:

The Part 35 regulations referred to in the comment that are not matters of compatibility apply only to licensees within the jurisdiction of the adopting agency, i.e., there are no transboundary implications. Part 35 regulations generally address requirements imposed on users, not manufacturers or distributors. The exception is section 35.11 that specifies that a license is required to manufacture or distribute materials for medical use. However, the specific licensing requirements given in section 35.12 reference only users as described in sections 35.100, 35.200, 35.300, 35.400, 35.500, and 35.600. The requirements for manufacture and distribution are specified in sections 32.72 and 32.74. Since manufacturers or distributors in one jurisdiction may supply licensees in another jurisdiction, there are significant transboundary implications for these activities.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 19:

Note that Section 34.1 is classification 3.b while 34.1(b) and (c) are 3.a.

RESPONSE:

There are no sections identified as 34.1(b) and 34.1(c) in Part 34.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 20:

Why are the definitions for "permanent radiographic installation" and "storage area" classified as "3.b" - this seems to conflict with the "3.a" classification for Section 34.43(a) and (c).

RESPONSE:

The Working Group believes the designations are consistent with the Policy Statement. The definitions of "permanent radiographic installation" and "storage area" are not captured by Component 3.a (Category C) since their absence from a state's requirements would not create a conflict, duplication or gap and, thus, do not meet the compatibility criteria of the Policy Statement. Further, they were considered by the Working Group to be sufficiently well understood in common usage that they did not need to be redefined as regulatory definitions. With respect to 34.43(a) and (c) that deal with availability of survey instruments and surveys, the Working Group concluded, and continues to conclude, that their absence from a state's requirements would create a gap and, therefore, meet the criteria for Component 3.a (Category C).

DISPOSITION:

No changes were made as a result of these comments.

COMMENT 21:

The classifications established for Sections 34.4, 34.8, 34.11 and 34.32(l) seem inappropriate given the use of a footnote to establish what appears to be a conditional classification.

RESPONSE:

The footnote initially was intended to explain the rationale for the compatibility category assignment for each rule. For sections 34.8 and 34.32(l), the component assigned was 3.b (Category D) since they are OMB approval and Part 21-related, respectively. For 34.4 and 34.11, the component assigned was 3.a (Category C) with the footnote since maintenance of records and specific licensing requirements for radiographers were considered to be necessary given the fact that radiographers frequently work in more than one jurisdiction. Absence of these requirements in Agreement States would result in a gap in the nationwide regulation of agreement material.

DISPOSITION:

No changes were made to the compatibility categories as a result of this comment; however, to avoid further confusion the footnote was deleted.

COMMENT 22:

For Sections 34.24, 34.25, 34.26, 34.28, 34.30, 34.31, 34.32, 34.33, and 34.41, the "3.a" classification, which appears to allow states to create less restrictive regulations, raises questions as to what are the "essential objectives" of these requirements. Because 10 CFR 150.20 requires reciprocity general licensees to comply with the NRC requirements, a less restrictive state requirement would create problems in this circumstance.

RESPONSE:

The Working Group agrees with the concern expressed by the commenter relating to the possible establishment of a less restrictive requirement by an Agreement State and the impact on reciprocal recognition of licenses. The Working Group believes that by adopting and implementing the essential objectives of a regulation, an Agreement State will meet the intent of NRC's regulation and therefore will not be less restrictive.

DISPOSITION:

A definition of "essential objective" has been included in the Glossary to Handbook 5.9 and a more detailed explanation of this concept is included in Part VI (Additional Implementing Issues) of Handbook 5.9.

COMMENT 23:

For Section 34.44, "Supervision of Radiographer's Assistant," the "3.b" classification indicates states are not required to adopt this requirement. This seems inappropriate and a would create a significant health and safety concern.

RESPONSE:

Since the Working Group designated the definition of "radiographer's assistant" in section 34.2 as component 3.b (Category D), the same category here appears to be appropriate. An Agreement State should not be required to have radiographer's assistants if they wish to limit the cited duties to trainees for a limited time period. The Working Group believes this is an important flexibility matter and notes that at least one Agreement State does not have radiographer's assistants. If a state wishes to have such personnel, then these appear to be appropriate requirements. The Working Group, however, does not believe that by not having radiographer's assistants that a significant gap or conflict is created. Further, health and safety do not appear to be compromised if radiography is limited to radiographers and supervised trainees.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 24:

The definition of "authorized nuclear pharmacist" in section 35.2, section 35.6 (Human Research) and section 35.49 (sealed source suppliers) should be 3.a, not 3.b.

RESPONSE:

The Working Group reconsidered the compatibility categories for this definition and these sections. They are neither radiation protection standards as defined by the Policy Statement nor do they have significant and direct transboundary implications. Absence of this definition or these provisions would not create a conflict, duplication or gap in the

regulation of agreement material on a nationwide basis or create a situation that could cause an exposure of an individual in excess of regulatory limits. Therefore, the Working Group concluded that they did not meet the criteria for Component 3.a (Category C), nor did they meet the criteria to be identified as having particular health and safety significance.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 25:

There appears to be an inconsistency with respect to the compatibility level assigned to a requirement versus the associated recordkeeping requirement in Section 35.53.

RESPONSE:

The requirements to measure the activity of each dosage is fundamental for protection against gross overdoses of radiation and, thus, are identified as being of particular health and safety significance. The requirement to keep records does not meet the criteria to identify requirements of particular health and safety significance and it is covered generally in other sections of NRC regulations.

DISPOSITION:

No changes were made in response to this comment.

COMMENT 26:

In Part 36, all definitions except for that of "Irradiator" are classification "3.b" which creates general concern because of the nationwide use of irradiators by single corporations.

RESPONSE:

The Working Group recognizes the concern expressed by the commenter, and has reconsidered whether some or all of the definitions should be changed to Component 3.a (Category C). Following further review, the Working Group continues to conclude that the absence of the definitions in an Agreement state's requirements would not create a significant conflict, duplication or gap. The Working Group believes the definitions are sufficiently well understood in plain language terms that they do not need to be included in a state's regulatory definitions for purposes of compatibility.

DISPOSITION:

No changes were made in response to this comment.

COMMENT 27:

The classification for Section 36.13 is "3.b*" which specifies criteria as stringent as NRC's while the similar provision in Section 34.11 is "3.a" which appears to allow less restrictive requirements.

RESPONSE:

Both Component 3.a (Category C) and Component 3.b* (Category D, H&S - identification of a provision as having particular health and safety significance) mean that an Agreement State should adopt, at a minimum, the essential objectives of the regulation. While both provisions should be adopted by Agreement States, the different bases for these determinations lies in the regulated activity. In section 34.11, radiography frequently involves activities in multiple jurisdictions and consistent requirements on this class of licensee is needed to avoid conflicts or gaps resulting in a designation of Component 3.a (Category C). In contrast, section 36.13 applies to fixed irradiator installations and does not meet the objective criteria for compatibility Components 1, 2, 3.a or 3.a.S but does meet the Working Group's criteria for identification of a requirement of particular health and safety concern and the section is thus identified as Component 3.b* (Category D, H&S). In both instances, the Agreement State should adopt the essential objective of the NRC program element. The Working Group believes that by adopting and implementing the essential objectives of a regulation, an Agreement State will meet the intent of NRC's regulation and therefore will not be less restrictive.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 28:

For Sections 36.27, 36.35 and 36.55, the classification is "3.b" indicating the states are not required to adopt these requirements. This seems inappropriate and would create a significant health and safety vacuum.

RESPONSE:

The Working Group has reconsidered the compatibility categories for these three sections and agrees that section 36.27 should be identified as meeting the criteria for having particular health and safety significance, but not meeting the criteria for compatibility. The Working Group continues to believe that sections 36.35 and 36.55 should remain as Component 3.b (Category D). The source rack protection requirement in 36.35 does not meet the health and safety criteria and the personnel monitoring requirement in 36.55 is already covered by provisions in §20.1502.

DISPOSITION:

The compatibility classification for section 36.27 has been changed to Component 3.b* (Category D, H&S), identifying this provision as one with particular health and safety

significance. The compatibility categories for sections 36.35 and 36.55 were not changed in response to this comment.

COMMENT 29:

Does the comment for Sections 36.57, 36.59 and 36.63 indicate that only the quantitative values in these requirements are the "essential objectives" that must be adopted and be as stringent as NRC? If so, considering that the requirements are classified as "3.b*", what is expected of the other aspects of these requirements?

RESPONSE:

The Working Group re-evaluated the comments for these sections and concluded that the essential objective encompasses more than simply the numerical values in the regulations. The numerical values must be taken in the conte[illegible] whole provision. For example, in section 36.63, an essential objective of 20 mic[illegible] per centimeter is virtually meaningless. Likewise, an essential objective o[illegible]nance of pool water conductivity below a certain value is also incomplete. The essential objective is to ensure that the conductivity of the pool water does not exceed 20 (as opposed to another value such as 25 or 40) microsiemens per centimeter. However, a state should have flexibility to ensure its licensees meet this essential objective by whatever means is most effective for it.

DISPOSITION:

The "Comment" column of the rule charts in OSP Internal Procedure B.7 (Rev. 1) for these sections have been modified to indicate that the essential objectives of these requirement are more than simply the numerical values specified in the regulation.

COMMENT 30:

In the Part 39, all definitions except "logging supervisor" and "well logging" are classification "3.b" which creates concern given the significant transboundary implications associated with this licensed activity. This particularly seems conflicting to the Part 39 requirements using the definitions which are classification "3.a" or "3.b*".

RESPONSE:

The Working Group recognizes the concern expressed by the commenter, and has reconsidered whether some or all of the definitions should be changed to Component 3.a (Category C). Following further review, the Working Group continues to conclude that the absence of the definitions in an Agreement state's requirements would not create a significant conflict, duplication or gap. The Working Group believes the definitions are sufficiently well understood in plain language terms that they do not need to be included in a state's regulatory definitions for purposes of compatibility.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 31:

The classification for Section 39.13 is "3.b*" which specifies criteria as stringent as NRC's while the similar provision in Part 34.11 is classification "3.a" which appears to allow less restrictive requirements.

RESPONSE:

The Working Group has re-examined both sections cited by the commenter. They both specify specific licensing requirements for radiographer (34.11) and well-loggers (39.13). Because both types of licensed activity are routinely performed in more than one jurisdiction, lack of such requirements on the licensee by an Agreement State could cause a gap in the regulation of agreement material on a nationwide basis. The classification of 3.a (Category C) for 34.11 is appropriate and the classification of the analogous provisions in 39.13 should also be so classified.

DISPOSITION:

Section 39.13 was assigned to Component 3.a (Category C) to be consistent with the designation of Section 34.11.

COMMENT 32:

Sections 39.31(b), 39.33(a) and (c), 39.47 and 39.49 are classified "3.b" indicating the states are not required to adopt these requirements. This seems inappropriate and would create a significant health and safety concern.

RESPONSE:

The Working Group has reconsidered the compatibility category assignment for these sections and has concluded that they meet the criteria for assignment to Component 3.a (Category C) (note: section 39.31(b) was already so designated). Section 39.31(a) also was reconsidered and the Working Group concluded that it, too, met the criteria for Component 3.a (Category C).

DISPOSITION:

Sections 39.31(a), 39.33(a) and (c), and 39.49 were changed to Component 3.a (Category C) designations.

COMMENT 33:

The "3.a" classification, which appears to allow the states to create less restrictive regulations, for Sections 39.39, 39.43, 39.61, 39.63, 39.65, 39.73 and 39.75 raises questions on what is considered to be the "essential objectives" of these requirements. Because 10 CFR 150.20 requires reciprocity general licensees to comply with NRC requirements in Sections 39.31 through 39.77, less restrictive state requirements in these parts and in 39.33(b) and 39.35 will create compliance problems.

RESPONSE:

The Working Group recognizes the concern expressed by the commenter relating to the possible establishment of a less restrictive requirement by an Agreement State and the impact on reciprocal recognition of licenses. The Working Group believes that when an Agreement State adopts the essential objective of a program element it will, *de facto*, not be less restrictive and thus will remain compatible. The Working Group believes that by adopting and implementing the essential objectives of a regulation, an Agreement State will meet the intent of NRC's regulation and therefore will not be less restrictive.

DISPOSITION:

The discussion of "essential objective" in the Handbook, has been modified to clarify this point.

COMMENT 34:

The "3.b" classification for Section 40.20 seems somewhat inappropriate considering that the general licenses in 40.21, 40.22, 40.23 and 40.25 must be included.

RESPONSE:

The Working Group reconsidered the compatibility categories for these sections and concluded that they do not meet the objective criteria of the policy statement for inclusion in Component 3.a (Category C) nor do they meet the Working Group's criteria for identification as having particular health and safety significance. Therefore, these sections are not needed for purposes of compatibility.

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 35:

The "3.a" classification for Sections 40.25 and 40.60 raise questions on what is considered to be the "essential objectives" in these requirements. "Essential objective" should be defined or a guideline for use developed.

RESPONSE:

The Working Group agrees with the comment.

DISPOSITION:

A definition of "essential objective" has been added in the Glossary to the Handbook and the discussion of this term in the body of the Handbook has been modified to clarify its use.

COMMENT 36:

How are Sections 40.34(a)(1) and 40.35(d) classified?

RESPONSE:

These sections were inadvertently omitted from the tables and are have been assigned to Component 3.b (Category D).

DISPOSITION:

These sections were added to the tables.

COMMENT 37:

The "3.b" classifications for Sections 40.34(b), 40.36(e) and (f), 40.41, 40.42(k), 40.62 and 40.71, indicating that states are not required to adopt these requirements, seem inappropriate and would create a significant health and safety concern.

RESPONSE:

The Working Group reconsidered the compatibility categories for these sections and continues to conclude, with the exception of section 40.42(k), that they do not meet the objective criteria for Components 1, 2, 3.a or 3.a.S (Categories A, B or C) nor do they meet the criteria for identification as having particular health and safety significance. The Working Group also concluded that section 40.42(k) did not meet the compatibility criteria, but did meet the criteria for identification as having particular health and safety significance.

DISPOSITION:

The compatibility category of section 40.42(k) remains unchanged as Component 3.b (Category D), but it is identified as having particular health and safety significance. The compatibility categories of the other sections were not changed as a result of this comment.

COMMENT 38:

The classification for Section 40.61(c) is "3.b" while the similar provision in Part 34.4 is classified "3.a."

RESPONSE:

The Working Group reconsidered the compatibility categories for each of these sections and continues to conclude that section 34.4, which applies to radiography, should be similarly adopted by all jurisdictions to prevent conflicts and gaps since licensees operate in more than one jurisdiction. The Working Group concluded that the similar provision in Part 40, applicable to source material, generally would apply at a fixed installation where

records are not subject to the same type of conditions as those for radiography and, therefore, does not meet the criteria for compatibility component 3.a (Category C).

DISPOSITION:

No changes were made as a result of this comment.

COMMENT 39:

In Section 71.4, the definitions of "close reflection by water," "fissile material," "normal form radioactive material," and "optimum interspersed hydrogenous moderation" pertain to fissile material which is reserved for NRC. These should be classified as either "NRC" or "2."

RESPONSE:

It should be noted that NRC reserves regulatory authority over fissile (special nuclear) materials only if the quantity involved is sufficient to form a critical mass, or greater. Agreement States exercise regulatory authority over lesser quantities. Therefore, the Working Group does not consider the category of "NRC" for the definition of the term "fissile material" appropriate. The term "fissile material" is used in sections 71.10 and 71.12, both of which are assigned to Component 2 (Category B) and the Working Group has concluded that this definition meets the criteria for this compatibility category as well.

The term "normal form radioactive material," applies to byproduct, source, or special nuclear (fissile) material. Agreement States exercise regulatory authority over byproduct and source material and over special nuclear (fissile) material in quantities not sufficient to form a critical mass. Therefore, the category of "NRC" is not appropriate. The definition of "special form radioactive material" meets the criteria for, and is assigned to, Component 2 (Category B) and since "normal form" is simply radioactive material in any form other than "special form," the Working Group concluded that it also met the criteria for Component 2 (Category B).

The terms "close reflection by water," and "optimum interspersed hydrogenous moderation" are not used in any regulation that the Agreement States need to adopt for purposes of compatibility. The regulations in which the terms are used apply to regulatory concerns reserved exclusively to NRC and, therefore, meet the criteria for being designated "NRC." Since the definitions do not impose regulatory requirements, Agreement States may adopt such definitions as long as they are essentially identical and would not create a regulatory conflict.

DISPOSITION:

The compatibility categories for the definitions of "fissile material" and "normal form radioactive material" were changed from 3.b (Category D) to 2 (Category B). The definitions of "close reflection by water" and "optimum interspersed hydrogenous moderation" were changed from 3.b (Category D) to NRC.

COMMENT 40:

Many definitions in 10 CFR Part 61 previously classified as Division 1 are now category 3.b. (D), including such terms as "explosive material," "pyrophoric liquid," and "stability." We believe the terms should be at least a 3.a. (C). In addition, 61.23, 61.42, 61.43, and 61.61 are 3.b.; we believe these provisions should be retained in Agreement State Programs.

RESPONSE:

The Working Group reconsidered the categorization of the definitions described in the comment above, applying criteria based on the Policy Statement. The Working Group concluded after re-examination that its initial categorizations were appropriate. The Working Group also reconsidered the categorization of the provisions in 10 CFR 61.23, 61.42, 61.43 and 61.61. The Working Group concluded that revisions should be made to 10 CFR 61.23, 61.42, and 61.43 (See Disposition below). In particular, portions of 61.23 and 61.43 were identified as meeting the criteria for having particular health and safety significance. The Working Group concluded that 61.61 did not meet either the compatibility criteria or the criteria for particular health and safety significance.

DISPOSITION:

10 CFR 61.42 was designated as H&S, and a comment was added for 61.43 to note that it is already covered by Part 20 provisions. Other changes addressed 61.23; "H&S" was assigned to paragraphs (a) through (h), NRC assigned to paragraphs (i) and (j) and "D" was assigned to paragraphs k and l.

COMMENT 41:

The decommissioning timeliness and financial assurance provisions are not treated consistently in the various 10 CFR Parts. The commenter specifically cited the differences between the classification of 10 CFR 70.25 and 70.38 and similar provisions in 10 CFR Parts 30 and 40.

RESPONSE:

The Working Group reconsidered all provisions related to the comment above. The Working Group concluded after re-examination that 70.25 and 70.38 should be changed to comport with similar provisions in Parts 30 and 40.

DISPOSITION:

The classifications for 70.25 were changed to D (formerly 3.b) with paragraphs (a), (b), and (d) also assigned "H&S;" 70.38 was changed to D with paragraphs (c), (d), (e), (g), (h) and (k) also assigned as "H&S."

COMMENT 42.

Regulations in Part 71 pertaining to quality assurance requirements that affect Type B package users, such as Sections 71.103, 71.105, 71.109, and 71.111, should be classified "3.a" rather than "3.b." Sections 71.113 (document control) and 71.115 (control of purchased material, equipment and services) should be added to the charts and classified "3.a" and "3.b," respectively.

RESPONSE:

The Working Group concluded that Subpart H addresses administrative activities that provide assurance that NRC licensees will meet the safety standards contained in Part 71 and that these administrative matters are strictly between NRC and its licensees. Likewise, administrative requirements imposed by an Agreement State on its licensees is strictly a matter between the State and its licensees. Therefore, the Working Group concluded that the Subpart H provisions did not meet the criteria for Component 3.a (Category C) and, therefore, are assigned to Component 3.b (Category D). These provisions also did not meet the Working Group's criteria for identification as having particular health and safety significance.

DISPOSITION:

No changes in compatibility category were made in response to this comment. Sections 71.113 and 71.115 that were inadvertently omitted from the tables have been included as Component 3.b (Category D).

COMMENT 43.

Staff notes that Sections 71.18, 71.20, and 71.22 are assigned classification "NRC." These Sections provide general licenses to transport fissile material, however, the general licenses are provided only for NRC licensees.

RESPONSE:

Since the Agreement States have regulatory authority over fissile materials in quantities not exceeding the formula specified in 10 CFR 150.11, an Agreement State licensee presumably could have occasion to transport fissile material under circumstances addressed by these Sections. However, since Agreement State licensees are not granted a general license by the NRC regulations and the Agreement States should not adopt equivalent regulations for regulations classified "NRC," a regulatory gap is created. The Working Group has reconsidered this issue and, based on NRC's limitation of issuance of the general licenses only to licensees of the Commission, has concluded that these sections do not meet the criteria for "NRC" or for Components 1, 2, 3.a or 3.a.S (Categories A, B or C). Nor do they meet the Working Group's criteria for identification as having particular health and safety significance.

DISPOSITION:

These sections have been assigned to Component 3.b (Category D) with the stipulation that if a State does adopt such provisions that they must be essentially identical to those of NRC.

ATTACHMENT 3

Revisions Recommended to the

Final Policy Statement on Adequacy and Compatibility of Agreement State Programs

by

The Joint NRC-Agreement State Working Group
for
Development of Implementing Procedures

January 29, 1997

Key:

Text to be deleted is indicated by ~~strikeout~~.

Text to be inserted is indicated by redline.

POLICY STATEMENT ON ADEQUACY AND COMPATIBILITY OF AGREEMENT STATE PROGRAMS

PURPOSE

Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, provides for a special Federal-State regulatory framework for the control of radioactive materials under which the NRC, by agreement with a State, relinquishes its authority in certain areas to the State government as long as the State program is adequate to protect public health and safety and compatible with the Commission's program. Section 274 further directs the Commission to periodically review State programs to ensure compliance with provisions of Section 274. This Policy Statement presents the Nuclear Regulatory Commission's policy for the determination of the adequacy and compatibility of Agreement State programs established pursuant to Section 274 of the Atomic Energy Act (AEA) of 1954, as amended. This Policy Statement is intended to clarify clarifies the meaning and use of the terms "adequate to protect the public health and safety" and "compatible with the Commission's regulatory program" as applied to the Agreement State program. The Policy Statement also describes the general framework that the Commission will be used to in determining identify those NRC program elements[1] that Agreement State programs should implement to be adequate to protect the public health and safety and to be compatible with the Commission's regulatory program. Finally, the Policy Statement reflects principles discussed in the Commission's Statement of Principles and Policy for the Agreement State Program which should be considered in conjunction with this Policy Statement.

This Policy Statement is intended solely as guidance for the Commission and the Agreement States in the implementation of the Agreement State program. This Policy Statement does not itself impose legally binding requirements on the Agreement States. In addition, nothing in this Policy Statement expands the legal authority of Agreement States beyond that already granted to them by Section 274 of the Atomic Energy Act and other relevant legal authority. Implementation procedures adopted pursuant to this Policy Statement shall be consistent with the legal authorities of the Commission and the Agreement States.

BACKGROUND

The terms "adequate" and "compatible" constitute core represent fundamental concepts in the Agreement State program authorized in 1959 by Section 274 of the Atomic Energy Act of 1954, as amended (AEA). Subsection 274d. states that the Commission shall enter into an Agreement under subsection b., discontinuing NRC's regulatory authority over certain materials in a State, provided that the State's program is adequate to protect the public health and safety and compatible, in all other respects, with the Commission's regulatory program. Subsection 274g. authorizes and directs the Commission to cooperate with States in the formulation of standards to assure that State and Commission standards will be coordinated and compatible. Subsection 274j.(1) requires the Commission to review periodically the Agreements and actions taken by

---

[1] For the purposes of this Policy Statement, "program element" or "element" means any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons, that contributes to implementation of that program including regulations adopted and promulgated.

States under the Agreements to ensure compliance with provisions of Section 274. In other words, the Commission must review the actions taken by States under the Agreements to ensure that the programs continue to be adequate to protect public health and safety and compatible with the Commission's program.

Section 274 of the AEA requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." These separate findings are based on consideration of two different objectives. First, an Agreement State program should provide for an acceptable level of protection of public health and safety in an Agreement State (the "adequacy" component). Second, the Agreement State program should ensure that its program serves an overall nationwide interest in radiation protection (the "compatibility" component). As discussed in more detail below, an "adequate" program should consist of those program elements necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. A "compatible" program should consist of those program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications. Program elements for adequacy focus on the protection of public health and safety within a particular State, whereas program elements for compatibility focus on the impacts of an Agreement State's regulation of agreement materials on a nationwide basis or its potential effects on other jurisdictions.

In identifying those program elements for adequate and compatible programs, or any changes thereto, the Commission will seek the advice of the Agreement States and will consider such advice in its final decision.

~~A~~——*ADEQUACY*

An Agreement State's radiation control program is adequate to protect the public health and safety if administration of the program provides reasonable assurance of protection of the public health and safety in regulating the use of source, byproduct, and small quantities of special nuclear material (hereinafter termed "agreement material") as identified by Section 274b. of the AEA. The level of protection afforded by the program elements of 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. The overall level of protection of public health and safety provided by a State program should be equivalent to, or greater than, the level provided by the NRC program. To provide reasonable assurance of protection of public health and safety, an Agreement State program should contain five essential program elements, identified below, that The Commission will use ~~the five elements, identified below,~~ to define the scope of its reviews of ~~the~~ Agreement State programs. The Commission also will also consider, when appropriate, other aspects program elements of an Agreement State ~~program, such as elements or regulations,~~ which appear to affect the program's ability to provide reasonable assurance of public health and safety protection. Such consideration will occur only if concerns arise.

~~1.~~ A. LEGISLATION AND LEGAL AUTHORITY

State statutes should:

~~a.~~ 1. authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under an Agreement with the ~~NRC~~ Commission;

b. authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of the public health and safety;

c. authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and

d. be otherwise consistent with Federal statutes, as appropriate, such as Public Law 95-604, The Uranium Mill Tailings Radiation Control Act (UMTRCA).

In addition, the State should have existing legally enforceable measures such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of the public health and safety in the regulation of agreement materials in the State. 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. In adopting such requirements, Agreement States should adopt the essential objectives of those of the Commission.

2. B. LICENSING

The State should conduct appropriate evaluations of proposed uses of agreement material, before issuing a license, to assure that the proposed licensee's operations can be conducted safely. Licenses should provide for a reasonable assurance of public health and safety protection in relation to the licensed activities.

3. C. INSPECTION AND ENFORCEMENT

The State should periodically conduct inspections of licensed activities involving agreement material to provide reasonable assurance of safe licensee operations and to determine compliance with its regulatory requirements. When determined to be necessary by the State, the State should take timely enforcement action against licensees through legal sanctions authorized by State statutes and regulations.

4. D. PERSONNEL

The State should be staffed with a sufficient number of qualified personnel to implement its regulatory program for the control of agreement material.

5. E. RESPONSE TO EVENTS AND ALLEGATIONS

The State should respond to, and conduct timely inspections or investigations of incidents, reported events, and allegations involving agreement material within the State's jurisdiction to ~~ensure continuing~~ provide reasonable assurance of protection of the public health and safety.

~~B. COMPATIBILITY~~

An Agreement State radiation control program is compatible with the Commission's regulatory program when its program does not create conflicts, duplications, gaps, or other conditions which that would jeopardize an orderly pattern in the regulation of agreement material on a nationalwide basis. ~~In implementing this approach to compatibility, the Commission will use~~

the following three component approach: For purposes of compatibility, the State should address Categories A, B, and C identified below:

1. A. The Agreement State should adopt basic radiation protection standards, and the dose limits in 10 CFR 61.41 [3], that are essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards. BASIC RADIATION PROTECTION STANDARDS

For purposes of this Policy Statement, this category includes The term "basic radiation protection standards" meansing public dose limits, and radiation protection related concentration and release limits related to radiation protection in 10 CFR Part 20 that are generally applicable to all licensees, and the dose limits in 10 CFR 61.41[3]. The Agreement State should also adopt, in an essentially identical form, Also included in this category are a limited number of definitions, signs, labels and scientific terms which that are necessary for a common understanding of radiation protection principles among licensees, regulatory agencies, and members of the public. Such State standards should be essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards.

2. B. PROGRAM ELEMENTS WITH SIGNIFICANT TRANSBOUNDARY IMPLICATIONS The Agreement State should adopt regulations essentially identical to those of the NRC Commission for those areas of regulation that are related to activities involving significant transboundary implications. It is t

The Commission's intent to will limit this category to a small number of regulations program elements (e.g., transportation requirements regulations and sealed source and device registration certificates) that directly involve such activities directly. The Agreement State's program elements should be essentially identical to those of the Commission.

3. C. OTHER COMMISSION PROGRAM ELEMENTS For all other regulations and elements, the Commission will apply the following approach:

a. The Agreement State should adopt and implement essential objectives of certain These are other Commission regulations and program elements (e.g., reciprocity procedures) that are important for an Agreement State to have in order to avoid conflicts, duplications, gaps, or other conditions which that would jeopardize an orderly pattern in the regulation of agreement material on a nationalwide basis. Such Agreement State regulations or program elements program elements should embody the essential objective of need not be identical to the corresponding Commission regulations or program elements; in a few cases, however, Agreement State regulations must be at least as stringent as that of the Commission;

b.

---

[3] The Commission will implement this category consistent with its earlier decision in the LLW area to allow Agreement States flexibility to establish pre-closure operational release limit objectives, ALARA goals or design objectives at such levels as the State may deem necessary or appropriate, as long as the level of protection of public health and safety is at least equivalent to that afforded by Commission requirements.

D. PROGRAM ELEMENTS NOT REQUIRED FOR COMPATIBILITY

The Agreement State ~~should have~~ has the flexibility to adopt and implement program elements ~~based on those of the~~ Commission ~~regulations and program elements in addition to~~ (other than those ~~necessary to maintain compatibility, as~~ identified in ~~B.1, B.2, and B.3.a~~ A, B, and C above) ~~of other program~~ ; ~~and~~

~~c. An Agreement State may adopt and implement other regulations and elements within the State's jurisdiction that are not addressed by NRC.~~

~~All regulations and elements covered under this third component must~~

~~All~~ program elements of an Agreement State relating to agreement material should:

1. be compatible with those of the Commission (i.e., ~~must~~ should not create conflicts, duplications, gaps, or other conditions ~~which~~ that would jeopardize an orderly pattern in the regulation of agreement material on a nationalwide basis);

~~In addition, Agreement State regulations or program elements covered under this third component should not be adopted or implemented in such a manner that the State:~~

~~a.~~ not precludes, or effectively precludes, a practice[3] within the national interest without an adequate public health and safety or environmental basis related to radiation protection; or

~~b.~~ not precludes, or effectively precludes, the ability of the Commission to evaluate the effectiveness of the NRC and Agreement State programs for agreement material with respect to protection of public health and safety.

SUMMARY AND CONCLUSIONS

~~Finally, t~~ To foster and enhance a coherent and consistent nationalwide program for the regulation of agreement material, the Commission encourages Agreement States to adopt and implement ~~similar regulations and~~ program elements ~~which~~ that are patterned after those adopted and implemented by the Commission. However, the fact that an Agreement State's program is compatible with that of the Commission does not affect that State's obligation to maintain an adequate program as described in this Policy Statement.

By adopting the criteria for adequacy and compatibility as discussed in this Policy Statement the Commission ~~intends to~~ will provide Agreement States with a broad range of flexibility in the administration of an individual program. In doing so, the Commission ~~seeks to~~ allows Agreement States to fashion their programs so as to reflect specific State needs and

---

[3] "Practice" means a use, procedure, or activity associated with the application, possession, use, storage, or disposal of agreement material. The term "practice" is used in a broad and encompassing manner in this Policy Statement. The term encompasses both general activities involving use of radioactive materials such as industrial and medical uses and specific activities within a practice such as industrial radiography and brachytherapy.

preferences, recognizing the fact that Agreement States have responsibilities for radiation sources in addition to agreement material. The Commission intends to will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner as a result of the to maintain compatibility components. At the same time, requirements in these compatibility components categories will allow the Commission to ensure that an orderly regulatory pattern for the regulation of agreement material exists across the country nationwide. The Commission believes that this approach achieves a proper balance between the desire need for Agreement State flexibility and the need for coherent coordinated and compatible regulation of agreement material across the country.

ATTACHMENT 4

Adequacy and Compatibility of Agreement State Programs

Directive 5.9

Volume 5, Governmental Relations and Public Affairs
Adequacy and Compatibility of
Agreement State Programs
Directive 5.9

Contents

Adequacy and Compatibility of Agreement State Programs
Directive 5.9

Policy
(5.9-01)

It is the policy of the U.S. Nuclear Regulatory Commission to evaluate Agreement State Programs established pursuant to Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, for adequacy to protect public health and safety and compatibility with NRC's regulatory program.

Objectives
(5.9-02)

- To establish the process NRC staff will follow to determine when a proposed or final Commission regulation or program element should be adopted as a legally binding requirement by an Agreement State and whether adoption is required for the purpose of compatibility or health and safety as set out in the Policy Statement on Adequacy and Compatibility of Agreement State Programs. (1)

- To identify Commission regulations and program elements that must be implemented as legally binding requirements by an Agreement State to maintain a program that is adequate to protect public health and safety and compatible with NRC's regulatory program. (2)

- To describe how NRC staff should apply provisions of the Policy Statement to current and future Agreement State regulations and program elements. (3)

Organizational Responsibilities and Delegation of Authority
(5.9-03)

Executive Director for Operations (EDO)
(031)

Oversees the program to evaluate adequacy and compatibility of Agreement State programs.

Director, Office of State Programs (OSP)
(032)

- Reviews the adequacy and compatibility of Agreement State programs through the Integrated Materials Performance Evaluation Program (Management Directive 5.6). (a)

- Reviews, evaluates and determines, in coordination with other NRC offices, those NRC program elements that an Agreement State should adopt for compatibility or adequacy. (b)

- Assists in the review, evaluation, and determination of those NRC regulations that an Agreement State should adopt as a legally binding requirement for the purpose of compatibility or health and safety. (c)

- Coordinates, with other NRC offices, the review of Agreement State regulations and program elements. (d)

Office of the General Counsel
(033)

- Assists in the review, evaluation, and determination of those NRC program elements and regulations an Agreement State should adopt for the purpose of compatibility or health and safety. (a)

- Advises staff on findings regarding the adequacy and compatibility of Agreement State regulations and program elements. (b)

Director, Office of Nuclear Regulatory Research (RES)
(034)

- Reviews, evaluates, and determines those NRC regulations an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (a)

- Assists in the review, evaluation, and determination of those NRC program elements an Agreement State should adopt for compatibility or health and safety. (b)

Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(035)

Assists in the review, evaluation, and determination of those NRC program elements and regulations an Agreement State should adopt for the purpose of compatibility or health and safety.

Director, Office for Analysis and Evaluation of Operational Data (AEOD)
(036)

Assists in the review, evaluation, and determination of those NRC program elements and regulations an Agreement State should adopt for the purpose of compatibility or health and safety.

Regional Administrators
(037)

Assists in the review, evaluation, and determination of those NRC program elements and regulations an Agreement State should adopt for the purpose of compatibility or health and safety.

Applicability

(5.9-04)

The policy and guidance in this directive and handbook apply to all NRC employees who are responsible for and participate in the review and evaluation of Agreement State regulatory programs or are involved in development and promulgation of NRC regulations or program elements for byproduct, source, and special nuclear materials.

Handbook
(5.9-05)

Handbook 5.9 describes the criteria and the process that will be used to determine the compatibility and health and safety components of NRC regulations and program elements an Agreement State should adopt for an adequate and compatible program.

References
(5.9-06)

Title 10 of the Code of Federal Regulations

Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

"Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," dated [insert effective date].

"Final `Statement of Principles and Policy for the Agreement State Program' and `Procedures for Suspension and Termination of an Agreement State Program,' " dated [insert effective date].

ATTACHMENT 5

Adequacy and Compatibility of Agreement State Programs

Handbook 5.9

Part I
Introduction

Overview (A)

The Policy Statement on Adequacy and Compatibility of Agreement State Programs (Policy Statement) sets forth the approach that the Commission will use to determine those program elements that should be adopted by an Agreement State to maintain an adequate and compatible program. This handbook describes the specific criteria and process that will be used to identify the compatibility categories of those NRC program elements that should be adopted and implemented by an Agreement State for purposes of compatibility, as well as for identifying those program elements that have a particular health and safety significance. It further describes how NRC staff is to apply the provisions of the Policy Statement to current and future Agreement State program elements for purposes of compatibility. However, the overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, The Integrated Materials Performance Evaluation Program (IMPEP).

Policy Statement on Adequacy and Compatibility of Agreement State Programs (B)

An Agreement State radiation control program is compatible with the Commission's regulatory program when the State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of agreement material (source, byproduct, and small quantities of special nuclear material as identified by Section 274b. of the AEA) on a nationwide basis. As a general matter, compatibility focuses primarily on the potential effects of State action or inaction either on the regulation of agreement material on a nationwide basis or on other jurisdictions. The concept of compatibility does not, however, directly address matters of health and safety within a particular Agreement State; such matters are addressed directly under adequacy. Further, basic radiation protection standards and program elements with transboundary implications, although important for health and safety within the State, should be uniform nationwide for compatibility purposes. (1)

An Agreement State radiation control program is adequate to protect public health and safety if administration of the program provides reasonable assurance of protection of public health and safety in regulating the use of agreement material. The level of protection afforded by the program elements of 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. A subset of one of the five elements identified to help provide such reasonable assurance is legally binding requirements addressing protection of public health and safety within the State. (2)

Based on the Policy Statement, NRC program elements (including regulations) can be placed into four compatibility categories. In addition, NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. These are summarized below. (3)

Compatibility Category A (a)

NRC program elements in Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand these concepts. The language of such program elements adopted by an Agreement State should be essentially identical to that of NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B (b)

NRC program elements in Category B are those that apply to activities that have direct and significant transboundary implications. An Agreement State should adopt program elements essentially identical to those of NRC.

Compatibility Category C (c)

NRC program elements in Category C are those that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the NRC program elements.

Compatibility Category D (d)

NRC program elements in Category D are those that do not meet the compatibility criteria set forth in the Policy Statement and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (e)

These are NRC program elements that are not required for compatibility by the criteria of the Policy Statement (i.e., Category D), but that have been identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this category based on those of NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations.

Exclusive to the NRC (f)

These are NRC program elements that address areas that cannot be relinquished to Agreement States pursuant to the AEA.

Part II
Categorization Criteria

Several criteria are necessary to determine the compatibility category for NRC program elements. These are established in this part and are to be used in conjunction with the series of questions in Part III and the flow chart in Appendix A. Definitions for commonly used terms are compiled in Part VII (Glossary).

Criteria (A)

Compatibility Category A (1)

To be included in Category A, an NRC program element is to be generally applicable **and** is to be a dose limit or a related concentration or release limit or a scientific term, definition, sign, or label that is necessary to understand basic radiation protection principles (basic radiation protection standard). (a)

Examples include, but are not necessarily limited to: (b)

- public dose limits (e.g., 10 CFR 20.1301) plus any regulation that relates directly to these dose limits (i)
- concentration and release limits (ii)
- occupational dose limits (e.g., 10 CFR 20.1201) plus any regulation that directly relates to these dose limits (iii)
- dose limits in 10 CFR 61.41 (iv)
- radiation symbol (v)
- caution signs and labels (vi)
- scientific terms (e.g., conventional and Système Internationale units, definitions of types of radioactive material) (vii)
- definitions needed for common understanding (e.g., restricted area, year, stochastic) (viii)

Compatibility Category B (2)

To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. (a)

Examples include, but are not necessarily limited to: (b)

- transportation requirements (e.g., low level radioactive waste manifests, packaging requirements) (i)

- requirements for approval of products that are distributed nationwide (e.g., sealed sources and devices) (ii)
- definitions of products (e.g., sources and devices) that licensees routinely transport in multiple jurisdictions (iii)
- content and format of sealed source and device registration certificates. (iv)

Compatibility Category C (3)

To be included in Category C, an NRC program element is to be one, the essential objective(s) of which an Agreement State should adopt to avoid conflicts, duplications, or gaps in the regulation of agreement material on a nationwide basis and that, if not adopted, would result in an undesirable consequence. Definitions of "conflict," "duplication," and "gap" are included in Part VII (Glossary). (a)

Examples of undesirable consequences include, but are not necessarily limited to: (b)

- exposure to an individual in a different jurisdiction in excess of the basic radiation protection standards established for compatibility in Category A, above; (i)
- undue burden on interstate commerce (e.g., additional recordkeeping or training requirements); (ii)
- preclusion of an effective review or evaluation by the Commission of the NRC and Agreement State programs for agreement material with respect to protection of public health and safety; (iii)
- preclusion of a practice in the national interest; (iv)
- absence or impairment of effective communication; (v)
- lack of minimum level of safety for agreement material - containing products distributed nationwide; (vi)
- disruption of the regulation of agreement material on a nationwide basis. (vii)

Examples of program elements in this category include, but are not necessarily limited to: (d)

- reports of lost or stolen agreement material or misadministrations (i)
- radiation surveys for industrial radiographers and well-loggers (ii)
- documents and records required at temporary job sites. (iii)

Compatibility Category D (5)

NRC program elements that do not meet any of the criteria of Category A, B, or C, above, are Category D and are not required for compatibility purposes. (a)

Health and Safety (6)

An NRC program element that is not required for compatibility **and** could result directly (i.e., 2 or fewer failures[1]) in an exposure to an individual in excess of the basic radiation protection standards in Category A if its essential objectives were not adopted by an Agreement State is identified as having particular health and safety significance. (a)

Examples of such program elements include, but are not necessarily limited to: (b)

- requirement for irradiator interlocks (i)
- safety checks for medical teletherapy facilities (ii)
- package opening procedures. (iii)

---

[1] The concept embodied by "2 or fewer failures" is that if the essential objectives of the program element were not adopted and implemented, then an event could occur that would not have taken place were the essential objectives adopted. This alone, or in conjunction with at most one other event, could result in exposure of an individual in excess of limits set by basic radiation protection standards.

Part III
Categorization Process for NRC Program Elements

The protocol to be used to assign a compatibility category to NRC program elements or to identify a program element as having particular health and safety significance is diagramed in the flow chart in Appendix A. The basis of the flow chart is a series of questions that are listed below. Each program element is tested by asking the series of questions below in the order given. The answers to these questions determine the compatibility category for each NRC program element or identify it as having particular health and safety significance. (A)

Question (1) Do the essential objectives of the program element address a regulatory area reserved solely to the authority of the NRC? If the response to the question is "yes", the compatibility category is "NRC." If the response to the question is "no," then proceed to Question (2). (1)

Question (2) Do the essential objectives of the program element address or define a basic radiation protection standard as defined by the Policy Statement or is it a definition, term, sign, or symbol needed for a common understanding of radiation protection principles? If the response to this question is "yes", the compatibility category is "A." If the response to the question is "no", then proceed to Question (3). (2)

Question (3) Do the essential objectives of the program element address or define an issue that has a significant, direct transboundary implication? If the response to this question is "yes", the compatibility category is "B." If the response to the question is "no", then proceed to Question (4). (3)

Question (4) Would the absence of the essential objectives of the program element from an Agreement State program create a conflict or gap? If the response to this question is "yes", the compatibility category is "C". If the response to the question is "no", then the compatibility category is "D" and proceed to Question (5) to determine whether the program element should be identified as having particular health and safety significance. (5)

Question (5) Would the absence of the essential objectives of the program element from an agreement state program create a situation that could directly result in exposure to an individual in excess of the basic radiation protection standards found in compatibility category A? If the response to this question is "yes", the program element is not required for purposes of compatibility, but is identified as having particular health and safety significance. (6)

Part IV
Applicability to NRC Program Elements

Current NRC Program Elements (A)

The compatibility category and identification of particular health and safety significance for current Commission program elements that are applicable to the regulation of agreement materials are found in OSP Internal Procedure B.7 (Revision 1), "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." B.7 will be updated periodically as final rules are published.

Future NRC Regulations and Program Elements (B)

The compatibility category or identification of particular health and safety significance of a proposed rule is to be suggested at the time the rulemaking plan is formulated and is to be coordinated with the Agreement States according to Management Directive 6.3, "The Rulemaking Process." Staff is to use Management Directive 5.9 to determine the compatibility category or to identify particular health and safety significance for each draft rulemaking plan. OSP Internal Procedure B.7 (Revision 1) will be revised to incorporate the results of these determinations after the final rule or program element is adopted.

PART V
Applicability to Agreement State Program Elements

Current Agreement State Program Elements (A)

Regulations (1)

NRC regulations that had **not** been required for compatibility according to OSP Internal Procedure B.7, "Criteria for Compatibility Determinations," but, pursuant to the new Policy Statement, are included in compatibility categories A, B, or C or are identified as having health and safety significance should be adopted by the States with an effective date within three years of the effective date of the Policy Statement and implementing procedures. (a)

NRC regulations that had been required for compatibility according to OSP Internal Procedure B.7, but will **not** be required under the Policy Statement do not require any action by the States. (b)

In addition to the foregoing, if an Agreement State's regulations had been evaluated using OSP Internal Procedure B.7 and NRC's program review procedures prior to the effective date of the Policy Statement and found: (c)

- to be compatible, then no further action is required by the State; (i)
- to be **not** compatible, then the regulation deemed not compatible should be changed to conform to the Policy as expeditiously as possible, but not later than three years after the Policy's effective date; (ii)
- not to have adopted a regulation in compatibility category A, B or C, then the regulation should be adopted as expeditiously as possible, but not later than three years after the Policy's effective date or other date set by the Commission. (iii)

Program Elements (2)

Program elements other than regulations had not been identified previously for purposes of compatibility or for having health and safety significance. Such program elements now identified under the new Policy Statement should be adopted and implemented by the States within six months of the effective date of the Policy Statement and implementing procedures. If, due to other factors, an Agreement State cannot adopt and implement such a program element within the six month time frame, then the State and the Commission will agree upon a mutually acceptable timetable for adoption and implementation.

Future Agreement State Program Elements (B)

General (1)

Any changes to Agreement State program elements after the effective date of the Policy Statement should conform to the Policy Statement and implementing procedures set out in this handbook.

Future Regulations (2)

Proposed and final Agreement State regulations for agreement materials that will be submitted to the NRC will be reviewed in accordance with guidance provided in OSP Internal Procedures, D.7, "Reviewing State Regulations" and B.7 (Revision 1), "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." Results of the evaluation will be transmitted to the State in accordance with OSP internal procedures. *Note:* The overall determination of the adequacy and compatibility of individual Agreement State programs will be made in accordance with Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

Future New or Changed Program Elements (3)

NRC staff will review the adoption and implementation of any new or revised (non-regulation) program element by an Agreement State in accordance with the Integrated Materials Performance Evaluation Program review procedures set out in Management Directive 5.6 at the time of the next regularly scheduled review.

Evaluation of Applications for Agreement State Status (C)

NRC staff will apply the compatibility and health and safety categorization criteria and process in this handbook when reviewing the regulations and program elements contained in applications for Agreement State status submitted after the effective date of the Policy Statement.

PART VI
Additional Implementing Issues

Use of Management Directive 5.9 and Handbook 5.9 (A)

For IMPEP reviews of States in accordance with Management Directive 5.6, review teams will use Management Directive 5.9 to assess the status of the State's program elements with respect to those that should be adopted for compatibility or for health and safety reasons. Specific Agreement State regulations will be assessed as they are submitted by the State and a summary report will be provided to the IMPEP review team at the time of the State's next program review. However, the overall determination of adequacy and compatibility of individual Agreement State programs will be made in accordance with Management Directive 5.6, "Integrated Materials Performance Evaluation Program."

Essential Objectives (B)

The essential objective of each NRC program element in compatibility component C or identified as having particular health and safety significance should be adopted by the Agreement State. The term "essential objective" is defined in Part VII (Glossary). (1)

For those NRC program elements in compatibility category C, adoption of the essential objective(s) by an Agreement State means that the State is compatible with respect to that program element. (2)

For those NRC program elements identified as having particular health and safety significance, adoption of the essential objective(s) by an Agreement State means that the State is providing a level of protection equivalent to NRC with respect to that program element. A State has the latitude to adopt essential objectives that are more stringent. (3)

Essentially Identical Language (C)

Program elements in compatibility categories A and B should be adopted by Agreement States in identical or essentially identical language. The term "essentially identical" is defined in Part VII (Glossary). If language is used by an Agreement State that differs in any significant respect from that used in NRC regulations, the State should justify the equivalency of the language. An example of such language substitution that would not be considered significant would be use of the term "deterministic" in place of the term "non-stochastic." In this case, the former term is one commonly accepted in the international radiation protection community. Similarly, the use of Système Internationale (SI) units rather than conventional units is deemed essentially identical. Further, the adoption by States of more recent technical information (e.g., with respect to reference man) is viewed as being essentially identical. Finally, changes to reflect increased scope

of State authority (e.g., use of the term "radioactive material" in place of the term "byproduct material") or wording needed to conform to State administrative procedures (e.g., use of State agency name in place of "Commission") would not be considered significantly different.

Legally Binding Requirements (D)

Where appropriate, Agreement States should adopt program elements in compatibility categories A, B and C or those identified as having particular health and safety significance and applicable to all licensees in the form of a rule or other generic legally binding requirement in a manner consistent with the State's administrative laws. The use of generic requirements will help to avoid inconsistency and confusion that may result from the imposition of individual rquirements on a case-by-case basis. (1)

Further, requirements applicable to more than a few licensees also should be adopted in the form of a generic requirement. However, since the appropriate approach to such issues will depend on the types and numbers of licensees involved, the State's approach will be reviewed on a case-by-case basis. (2)

The mechanism used by the State should be legally binding on the licensee(s) and enforceable as law. Examples of such legally binding requirements may include license conditions (including licensee commitments referenced in "tie-down" conditions), orders or other mechanisms determined by the State to be legally binding and enforceable. The State has the responsibility of demonstrating that requirements adopted other than by regulation are legally binding. (3)

Time Frames for Adoption (E)

Commission regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame such that the effective date of the State requirement is not later than three years after the effective date of NRC's final rule. Certain circumstances (e.g., adoption of a basic radiation protection standard or other rule that will have significant impact on the regulation of agreement material on a nationwide basis, such as the low-level radioactive waste manifest) may warrant that the effective dates for both NRC licensees and Agreement State licensees be the same. In some cases, and with sufficient justification, health and safety considerations may warrant adoption by the States in less than the recommended three year (or six month) time frame. (1)

Program elements, other than regulations or equivalent legally binding requirements, that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by the Agreement States within six months of such designation by NRC. If, due to other factors, an Agreement State cannot adopt and implement such a program element within the six month time frame, then the State and the Commission will agree upon a mutually acceptable timetable for adoption and implementation. (2)

Areas Reserved Solely to NRC (F)

Certain regulatory areas cannot be relinquished to the States under 274.b agreements and remain the sole jurisdiction of the federal government. NRC rules promulgated to regulate these areas are reserved solely to the NRC. However, States may adopt program elements (including regulations) in, or otherwise address, these areas for the purpose of clarity and ease of communication. States may not adopt regulations, other legally binding requirements or program elements that would cause the State to regulate such activities.

Part VII
Glossary

Definitions (A)

Conflict means the essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis. (1)

Duplication means identical regulations or program elements apply to the same material at the same time. Note: this definition applies primarily to review of Agreement State regulations. (2)

Essential objective of a regulation or program element means the action that is to be achieved, modified or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area). (3)

Essentially identical means the interpretation of the text must be the same regardless of the version (NRC or Agreement State) that is read. (4)

Gap means the essential objectives of NRC regulations or program elements are absent from the Agreement State program and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis. (5)

Practice means a use, procedure, or activity associated with the application, possession, use, storage, or disposal of agreement material. The term "practice" is used in a broad and encompassing manner in the Policy Statement on Adequacy and Compatibility of Agreement State Programs. The term encompasses both general activities involving use of radioactive materials such as industrial and medical uses and specific activities within a practice such as industrial radiography and brachytherapy. (6)

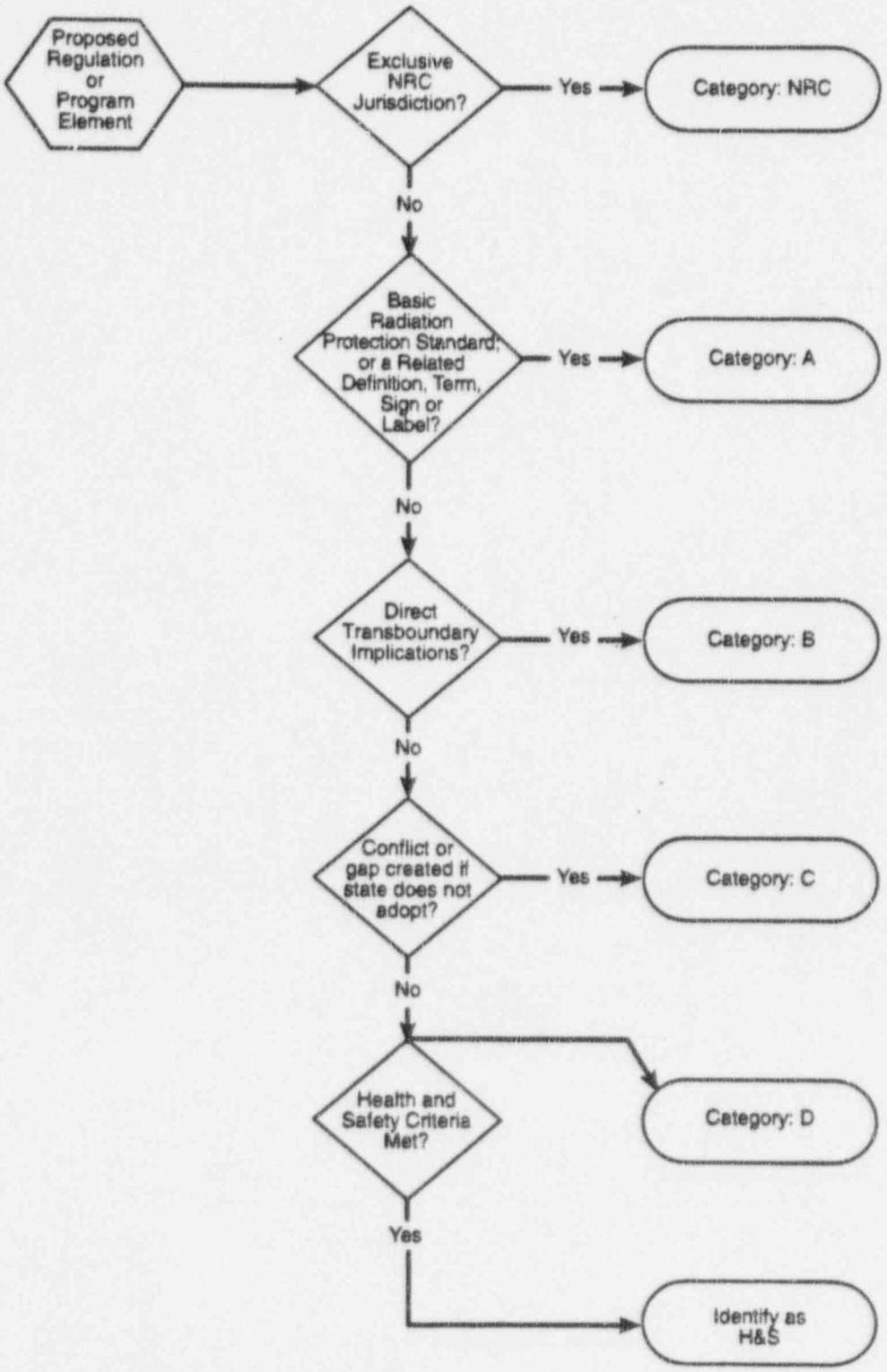
Program element means any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons, that contributes to implementation of that program. (7)

Transboundary means across jurisdictional boundaries within the United States. It does not mean between the United States and other nations. (8)

APPENDIX A

Flow Chart

Flow Chart


Proposed Regulation or Program Element
Exclusive NRC Jurisdiction?
Yes
Category: NRC
No
Basic Radiation Protection Standard; or a Related Definition, Term, Sign or Label?
Yes
Category: A
No
Direct Transboundary Implications?
Yes
Category: B
No
Conflict or gap created if state does not adopt?
Yes
Category: C
No
Health and Safety Criteria Met?
Category: D
Yes
Identify as H&S

ATTACHMENT 6

OFFICE OF STATE PROGRAMS

Pre-and Post-Agreement Activities

B.7 (Revision 1): Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements

1 Introduction

1.1 Purpose

This procedure provides guidance to NRC staff, Agreement States, and States seeking an Agreement on the compatibility categories assigned to NRC regulations and program elements and the identification of those regulations or program elements that have particular health and safety significance.

1.2 Background

1.2.1 The Policy Statement on Adequacy and Compatibility of Agreement State Programs sets forth the approach that the Commission will use to identify those program elements (including regulations) that Agreement State programs should implement to be adequate to protect public health and safety and to be compatible with the Commission's regulatory program.

1.2.2 Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," describes the criteria and process NRC staff follow to determine which NRC regulations and program elements should be adopted by an Agreement State for purposes of compatibility as well as purposes of health and safety. In accordance with Management Directive 5.9, each regulation and program element first is analyzed and categorized for purposes of compatibility and then identified if it has particular health and safety significance.

1.2.3 OSP Internal Procedure B.7 (Revision 1) has been developed and is maintained by the Office of State Programs to document, for use by NRC and State staff, the compatibility category for each NRC rule and program element and the identification of health and safety significance, as determined in accordance with Management Directive 5.9. In addition, Management Directive 5.9 provides that OSP Internal Procedure B.7 (Revision 1) should be updated at the time a new rule or program element is adopted.

2 Compatibility Categories & Health and Safety Identification

The tables in Section 3, below, contain a section-by-section analysis of regulations in Title 10 of the Code of Federal Regulations (10 CFR) and program elements that are applicable to the regulation of agreement materials. The analysis is based on the categorization criteria and process set out in Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs."

The Parts of 10 CFR for which tables are provided all have been analyzed section-by-section; those Parts that do not have a corresponding table have been determined to address areas in which Agreement States either do not have regulatory authority or that are applicable specifically to NRC's regulatory program and need not be addressed by an Agreement State. For the purpose of completeness, those Parts that totally address areas of exclusive NRC authority are listed in Table 1. Those Parts that generally are applicable specifically to NRC's regulatory program, but are not areas of exclusive NRC authority, are listed in Table 2. Any future changes to these determinations will be reflected in revisions to Tables 1 and 2 and to the individual section-by-section analysis tables in Section 3.

Table 1

Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas of Exclusive NRC Authority
Parts 10, 11, 25, 26, 50, 51, 52, 53, 54, 55, 60, 62, 72, 73, 74, 75, 76, 81, 95, 100, 110, 140, and 160.

Table 2

Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas That Generally Are Applicable Only to NRC's Regulatory Program
Parts 0, 1, 2, 4, 7, 8, 9, 12, 13, 14, 15, 16, 21[1], 170, and 171.

3 Regulation and Other Program Element Tables

In using the following tables, staff should be aware of the following points:

- The following sections are found in multiple Parts: *Purpose, Scope, Interpretations, Communications, OMB Approval, Violations, Criminal Penalties* and *Inspections*. They are all essentially identical from Part to Part. These requirements are not required for either compatibility or health and safety reasons. The State may elect to adopt similar sections based on its requirements.

- A number of terms are defined in more than one Part in 10 CFR. For purposes of consistency, the tables show the compatibility category for the definition in the most appropriate Part and refer to that Part at all other occurrences of the term

[1] The provisions in Part 21 derive from statutory authority in the Energy Reorganization Act, not the AEA, that does not apply to Agreement States. Therefore, this Part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the provisions of Part 21, States may not have the statutory authority to do so.

with the compatibility category shown in brackets. See, for example, the definition of "restricted area" in the table for Part 19, Section 19.3.

- Unless otherwise indicated in the tables, the compatibility category or identification of health and safety significance applies to the entire section of the Part. See, for example, the table for Part 20, Section 20.2003, where individual paragraphs are assigned different components.

Key to categories:

A = Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection that the State should adopt with (essentially) identical language.

B = Program element with significant direct transboundary implications that the State should adopt with essentially identical language.

C = Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.

D = Not required for purposes of compatibility; however, if adopted by the State, should be compatible with NRC.

NRC = Not required for purposes of compatibility; the regulatory area is reserved to NRC. However, a State may adopt these provisions for purposes of clarity and communication, as long as the State does not adopt regulations or program elements that would cause the State to regulate in these areas.

H&S = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

Addendum

Subsequent to the submission of the January 29, 1997, "Supplemental Report of the Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," the following revisions were made to the Internal Procedure B.7, Regulation and Other Program Element Tables.

For 10 CFR 40.32, the categorization was changed from "C" to "D" for paragraphs (a) through (g); paragraph (g) was assigned to "NRC;" and "H&S" was assigned to paragraphs (b) and (c).

For 10 CFR 61.23, "H&S" was assigned to paragraphs (a) through (h), NRC assigned to paragraphs (i) and (j) and "D" was assigned to paragraphs k and l. In addition, 10 CFR 61.42 and 61.43 were designated as H&S, and a comment was added for 61.43 to note that it is already covered by Part 20 provisions.

These changes have been incorporated into the attached tables.

Part 19 - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§19.1	Purpose	D	
§19.2	Scope	D	
§19.3	Definitions		
	Act	D	
	Commission	D	
	Exclusion	D	
	License	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Restricted area	[A]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category A.
	Sequestration	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Worker	C	This definition is needed for a common understanding of the term "worker" as used in the regulation of agreement material. The same definition should apply to persons working in more than one jurisdiction.
§19.4	Interpretations	D	
§19.5	Communications	D	
§19.8	Information c[illegible]tion requirement: OMB approval	D	
§19.11	Posting of notices to workers	C	These requirements are needed to provide a minimum level of information to workers and to assure that this information is consistent from one jurisdiction to another since workers may work in multiple jurisdictions.
§19.12	Instructions to workers	C	This provision should be adopted by States to assure a minimum level of required worker training since workers may work in multiple jurisdictions.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§19.13	Notification and reports to individuals	C	These requirements are needed to provide a minimum level of information to workers and to assure that this information is consistent from one jurisdiction to another since workers may work in multiple jurisdictions.
§19.14	Presence of representatives of licensees and workers during inspections	C	
§19.15	Consultation with workers during inspections	C	
§19.16	Requests by workers for inspections	C	
§19.17	Inspection not warranted; informal review	C	
§19.18	Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§19.20	Employee protection	D	
§19.30	Violations	D	
§19.31	Application for exemptions	D	
§19.32	Discrimination prohibited	D	
§19.40	Criminal penalties	D	

Part 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.1001	Purpose	D	
§20.1002	Scope	D	
§20.1003	Definitions		
	Absorbed Dose	A	
	Act	D	
	Activity	A	
	Adult	A	
	Airborne radioactive material	A	
	Airborne Radioactivity area	A	
	ALARA	A	
	Annual limit on intake (ALI)	A	
	Background Radiation	A	
	Bioassay (radio bioassay)	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Byproduct material	[A]	This definition also appears in 10 CFR §150.3(c). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Class	A	Also referred to as "Lung Class or Inhalation Class"
	Collective Dose	A	
	Commission	D	
	Committed dose equivalent	A	
	Committed effective dose equivalent	A	
	Controlled Area	D	
	Declared Pregnant Woman	A	
	Deep-dose equivalent	A	
	Department	D	
	Derived air concentration (DAC)	A	
	Derived air concentration-hour (DAC-hour)	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Dose or radiation dose	D	This definition is not required for compatibility. No definition is presented. Rather, several terms are referenced, which are later defined.
	Dose equivalent	A	
	Dosimetry processor	D	
	Effective dose equivalent	A	
	Embryo/fetus	A	
	Entrance or access point	C	This definition provides the minimum information needed for a common understanding and because differing definitions may jeopardize an orderly regulatory pattern in the regulation of agreement material.
	Exposure	A	
	External dose	A	
	Extremity	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Eye dose equivalent	A	The term, "Lens Dose Equivalent," if defined essentially identically to "Eye Dose Equivalent" is an acceptable substitute for this term.
	Generally applicable environmental radiation standards	A - States with authority to regulate uranium mill activities (11e.2 byproduct material) D - States without authority	This term is needed for common understanding in applying the dose limit requirements in 10 CFR 20.1301 and the reporting requirements in 10 CFR 20.2203. These sections reference requirements that are applicable to the uranium fuel cycle.
	Government agency	D	
	Gray	See 10 CFR §20.1004	This term is not defined in this section. Refer to the referenced section for the definition where it is assigned Compatibility Category A.
	High radiation area	A	
	Individual	A	
	Individual monitoring	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Individual monitoring devices	C	This definition provides the minimum information needed for a common understanding of the term and because inconsistent definitions may jeopardize an orderly regulatory pattern for the regulation of agreement material.
	Internal dose	A	
	License	D	
	Licensed material	D	
	Licensee	D	
	Limits	A	
	Lost or missing licensed material	B	This term and definition are needed for a common understanding in collecting and reporting information on regulation of agreement material on a nationwide basis.
	Member of the public	A	
	Minor	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Monitoring	A	
	Nonstochastic effect	A	The term, "deterministic," if defined essentially identically to "nonstochastic" is an acceptable substitute.
	NRC	D	
	Occupational Dose	A	
	Person	[C]	This definition also appears in 10 CFR §150.3(g). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category C.
	Planned special exposure	D	
	Public dose	A	
	Quality Factor	A	
	Quarter	D	
	Rad	See 10 CFR §20.1004	This term is not defined in this section. Refer to the referenced section for the definition where it is assigned to Compatibility Category A.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Radiation	A	
	Radiation area	A	
	Reference man	A	
	Rem	See 10 CFR §20.1004	This term is not defined in this section. Refer to the referenced section for the definition where it is assigned to Compatibility Category A.
	Respiratory protective device	C	
	Restricted area	A	
	Sanitary sewerage	A	
	Shallow-dose equivalent	A	
	Sievert	See 10 CFR §20.1004	This term is not defined in this section. Refer to the referenced section for the definition where it is assigned to Compatibility Category A.
	Site boundary	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Source Material	[A]	This definition also appears in 10CFR §150.3(i). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Special Nuclear Material	[A]	This definition also appears in 10CFR §150.3(j). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Stochastic effects	A	The term "probabilistic," if defined essentially identically to "stochastic" is an acceptable substitute.
	Survey	A	
	Total Effective Dose Equivalent (TEDE)	A	
	Unrestricted Area	A	
	Uranium Fuel Cycle	D	If a state chooses to adopt a definition of uranium fuel cycle, it must be essentially identical.

REGULATION SECTION	SECTION TITLE	COMPATIEILITY CATEGORY	COMMENTS
	Very High Radiation Area	A	
	Week	D	
	Weighting factor	A	
	Whole body	A	
	Working level (WL)	A	
	Working level month (WLM)	A	
	Year	A	
§20.1004	Units of radiation dose	A	
§20.1005	Units of radioactivity	A	
§20.1006	Interpretations	D	
§20.1007	Communications	D	
§20.1008	Implementation	D	
§20.1009	Information colletion requirements: OMB approval	D	
§20.1101	Radiation protection programs	D	H&S
§20.1201	Occupational dose limits for adults	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.1202	Compliance with requirements for summation of external and internal doses	A	
§20.1203	Determination of external dose from airborne radioactive material	A	
§20.1204	Determination of internal exposure	A	
§20.1205	Reserved		
§20.1206	Planned special exposures	D	
§20.1207	Occupation dose limits for minors	A	
§20.1208	Dose to an Embryo/fetus	A	
§20.1301	Dose limits for individual members of the public	A - paragraphs (a), (b), (c) and (e) D - paragraph (d)	
§20.1302	Compliance with dose limits for individual members of the public	D	H&S - paragraphs (a) and (b) only
Subpart E	Reserved		
§20.1501	Surveys and Monitoring - General	D	H&S

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.1502	Conditions requiring individual monitoring of external and internal occupational dose	D	H&S
§20.1601	Control of access to high radiation areas	D	H&S
§20.1602	Control of access to very high radiation areas	D	H&S
§20.1701	Use of process or other engineering controls	D	H&S
§20.1702	Use of other controls	D	H&S
§20.1703	Use of individual respiratory protection equipment	D	H&S
§20.1704	Further restrictions on the use of respiratory protection equipment	D	
§20.1801	Security of stored material	D	H&S
§20.1802	Control of material not in storage	D	H&S
§20.1901	Caution signs	A	
§20.1902	Posting requirements	A	In adopting these provisions, States have the flexibility to omit the wording "grave danger".

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.1903	Exceptions to posting requirements	D	
§20.1904	Labeling containers	A	
§20.1905	Exceptions to labeling requirements	A	
§20.1906	Procedures for receiving and opening packages	D	H&S
§20.2001	General requirements (Waste Disposal)	C	Agreement States should adopt the essential objectives of provision in order to eliminate confusion regarding the disposal of agreement material on a nationwide basis.
§20.2002	Method for obtaining approval of proposed disposal procedures	D	
§20.2003	Disposal by release into sanitary sewerage	A - paragraphs (a)(2) and (a)(3) C - paragraph (a)(4) D - paragraphs (a)(1) and (b)	H&S - (a)(1) only
§20.2004	Treatment or disposal by incineration	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.2005	Disposal of specific wastes	D	
§20.2006	Transfer for disposal and manifests	B	
§20.2007	Compliance with environmental and health protection regulations	D	
§20.2101	General provisions.	C	The use of SI units would be considered essentially identical.
§20.2102	Records of radiation protection programs	D	
§20.2103	Records of surveys	D	
§20.2104	Determination of prior occupational dose	D	If a state chooses to adopt "planned special exposure" this section should be adopted as a "C"
§20.2105	Records of planned special exposures	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.2106	Records of individual monitoring results	C - paragraphs (a) and (e) D - paragraphs (b), (c), (d) and (f)	Agreement States should adopt paragraphs (a) and (e) to eliminate confusion in obtaining information in support of implementation of basic radiation protection standards since individuals may receive exposure in more than one licensee's facility or in more than one jurisdiction.
§20.2107	Records of Dose to individual members of the Public	D	
§20.2108	Records of Waste Disposal	D	
§20.2110	Form of Records	D	
§20.2201	Reports of theft or loss of licensed material	C - paragraphs (a), (b), (d) and (e) D - paragraph (c)	These requirements are needed for a common understanding in collecting and reporting information on the regulation of agreement material on a nationwide basis.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.2202	Notification of Incidents	C - paragraphs (a), (b), (c) and (d) D - paragraph (e)	All of this provision, except paragraph (e), is needed for a common understanding in collecting and reporting information on the regulation of agreement material on a nationwide basis. Meeting the essential objective of this regulation for the purpose of compatibility means the State should adopt the numerical values noted in the regulation as the minimum level acceptable. If state adopts planned special exposure, then the state should adopt paragraph (e).
§20.2203	Reports of exposures, etc, exceeding the limits.	C - paragraphs (a) and (b) D - paragraph (d) NRC - paragraph (c)	Paragraphs (a) and (b) provide requirements that are needed for a common understanding in collecting and reporting information on the regulation of agreement material on a nationwide basis.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.2204	Reports of Planned special exposures	D	If state adopts planned special exposure, then the state should adopt this provision.
§20.2205	Reports to individuals of exceeding dose limits	C	
§20.2206	Reports of Individuals Monitoring	D - paragraphs (a)(2), (a)(6), (a)(7), (b) and (c) NRC - (a)(1), (a)(3), (a)(4), and (a)(5)	
§20.2301	Applications for Exemptions	D	
§20.2302	Additional Requirements	D	
§20.2401	Violations	D	
§20.2402	Criminal Penalties	D	
Appendix A	Protection Factors for Respirators	C	Agreement States should adopt this provision because it provides the minimum acceptable level of protection to be afforded by respirators.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
Appendix B (Tables 1,2, & 3)	Annual Limits on Intake (ALIs), Derived Air Concentrations (DACs), of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage	A	
Appendix C	Quantities of licensed materials requiring labeling	A	
Appendix D	United States Nuclear Regulatory Commission Offices	D	
Appendix E	Reserved		
Appendix F	Requirements for Low-level Waste Transfer for disposal at land disposal facilities and Manifest	B	The provisions are needed in order to provide consistency in regulating agreement material which cross multiple jurisdictions.
Appendix G	Requirements for Low-level radioactive waste intended for disposal at land disposal facilities and manifests	B	These provisions are needed by Agreement States to provide consistency in regulating agreement material which cross multiple jurisdictions.

Part 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.1	Scope	D	
§30.2	Resolution of Conflict	D	
§30.3	Activities requiring license	C	This requirement is needed for common understanding regarding activities requiring a license.
§30.4	Definitions		
	Act	D	
	Agreement State	[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.
	Alert	A	
	Byproduct material	[A]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Commencement of construction	D	
	Commission	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Curie	[A]	This definition also appears in 10 CFR §20.1005(b). For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category A.
	Decommission	C	This definition is needed for effective communication regarding regulation of agreement material on a nationwide basis.
	Dentist	[D]	This definition also appears in 10CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category D.
	Department and Department of Energy	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Effective dose equivalent	[A]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category A.
	Government agency	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	License	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Medical use	[C]	This definition also appears in 10CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category C.
	Microcurie	D	
	Millicurie	D	
	Person	[C]	This definition also appears in 10 CFR §150.3(g). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category C.
	Physician	[D]	This definition also appears in 10CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category D.
	Podiatrist	[D]	This definition also appears in 10CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category D.
	Principal activities	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Production facility	[NRC]	This definition also appears in 10 CFR §150.3(h). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category NRC.
	Radiographer	[C]	This definition also appears in 10 CFR §34.2. For purposes of compatibility, the language of the Part 34 definition should be used and it is assigned to Compatibility Category C.
	Radiographer's assistant	[D]	This definition also appears in 10 CFR §34.2. For purposes of compatibility, the language of the Part 34 definition should be used and it is assigned to Compatibility Category D.
	Radiography	[B]	This definition also appears in 10 CFR §34.2. For purposes of compatibility, the language of the Part 34 definition should be used and it is assigned to Compatibility Category B.
	Research and development	D	
	Sealed source	B	This definition is needed for a common understanding because of transboundary effects.
	Site area emergency	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Source material	[A]	This definition also appears in 10 CFR §150.3(i). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Special nuclear material	[A]	This definition also appears in 10 CFR §150.3(j). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	United States	D	
	Utilization facility	[NRC]	This definition also appears in 10 CFR §150.3(l). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category NRC.
§30.5	Interpretations	D	
§30.6	Communications	D	
§30.7	Employee protection	D	
§30.8	Information collection requirements: OMB approval	D	
§30.9	Completeness and accuracy of information	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.10	Deliberate misconduct	D	
§30.11	Specific exemptions	D	
§30.12	Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts	B	This provision should be adopted by Agreement States in an essentially identical manner since it is required by Federal law.
§30.13	Carriers	B	
§30.14	Exempt concentrations	B	
§30.15	Certain items containing byproduct material	B	
§30.16	Resins containing scandium-46 and designed for sand-consolidation in oil wells	B	
§30.18	Exempt quantities	B	
§30.19	Self-luminous products containing tritium, krypton-85, or promethium-147	B	
§30.20	Gas and aerosol detectors containing byproduct material	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.31	Types of licenses	C	This provision is needed to for effective communication regarding the different types of licenses.
§30.32	Application for specific licenses	C - paragraph (g) D - paragraphs (a), (b), (c), (d), (e), (f), (h) and (i)	H&S - paragraph (i) only
§30.33	General requirements for issuance of specific licenses	D	H&S - paragraphs (a)(2) and (a)(3) only
§30.34	Terms and conditions of licenses	C - paragraph (b) D - paragraphs (a), (c), (d), (e)(2), (e)(4), (f), (g) & (h) NRC - paragraphs (e)(1) & (e)(3)	The essential objective(s) of paragraph (b) should be adopted by Agreement States because of transboundary effects in transferring material through multiple jurisdictions and to avoid conflicts and confusion in regulation of agreement material on a nationwide basis.
§30.35	Financial assurance and recordkeeping for decommissioning	D	H&S - paragraphs (a), (b) and (d) only States are given flexibility to allow different dollar amounts based upon jurisdiction and local conditions.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.36	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas	D	H&S - paragraphs (c), (d), (e), (g), (h), (j) and (k) only
§30.37	Application for renewal of licenses	D	
§30.38	Application for amendment of licenses	D	
§30.39	Commission Action on applications to renew or amend	D	
§30.41	Transfer of byproduct material	C	This provision is needed for coherent regulation of agreement material on a nationwide basis.
§30.50	Reporting Requirements	C - paragraphs (a), (b) and (c), except D - paragraph (c)(3)	States have the flexibility to require additional event reporting information. This information would depend on local conditions, laws, etc.
§30.51	Records	C - paragraphs (a) & (b) D - paragraph (c)	The time required for record retention under paragraph (b) may vary in accordance with the type of activity being licensed.
§30.52	Inspections	D	
§30.53	Tests	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§30.55	Tritium reports	[NRC]	The provision in this section also appears in 10 CFR 150.19 where it is applicable to licensees of Agreement States. It is assigned to Compatibility Category NRC since it requires reports to NRC.
§30.61	Modification and revocation of licenses	D	
§30.62	Right to cause the withholding or recall or byproduct material	D	
§30.63	Violations	D	
§30.64	Criminal penalties	D	
§30.70	Schedule A - exempt concentrations table	B	
§30.71	Schedule B - exempt quantity table	B	
§30.72	Schedule C- Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release	D	H&S

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
Appendix A	Criteria Relating to Use of Financial tests and Parent Company Guarantees for Providing Reasonable Assurance of funds for Decommissioning	D	The amount of financial assurance required should reflect the current economic conditions at time of decommissioning.
Appendix B	Quantities of Licensed Material Requiring Labeling	B	
Appendix C	Criteria Relating to Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning	D	

Part 31 - GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATERGORY	COMMENTS
§31.1	Purpose and Scope	D	
§31.2	Terms and Conditions	D	
§31.3	Certain devices and equipment	B	Agreement States should adopt this provision because it contains requirements for devices and equipment which are distributed nationwide.
§31.4	Information collection requirements: OMB approval	D	
§31.5	Certain measuring, gauging or controlling devices	D	Agreement States have the flexibility to authorize the use of these devices under a specific license rather than by general license.
§31.6	General license to install devices generally licensed in § 31.5	C	Agreement States should adopt this provision because it recognizes the need for reciprocity of licenses from one jurisdiction to another for this activity. States may require notification as a part of these provisions.
§31.7	Luminous safety devices for use in aircraft	B	Agreement States should adopt this provision because it contains requirements for devices that are distributed nationwide and because of their nature they frequently cross multiple jurisdictions.
§31.8	Americium-241 in the form of calibration or reference sources	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATERGORY	COMMENTS
§31.9	General license to own byproduct material	D	
§31.10	General license for strontium 90 in ice detection devices	B	Agreement States should adopt this provision because it contains requirements for devices that are distributed nationwide.
§31.11	General license for use of byproduct material for certain in vitro clinical or laboratory testing	D	Agreement States have the flexibility to authorize the use of these materials under a specific license.
§31.12	Maintenance of records	D	
§31.13	Violations	D	
§31.14	Criminal penalties	D	

Part 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.1	Purpose and Scope	D	
§32.2	Definitions		
	Dose commitment	[A]	This term and definition are superseded by the new term and definition in 10 CFR Part 20, "committed dose equivalent," which is stated in more current radiation protection terminology and is assigned to compatibility Category A. The Part 20 term and definition should be used for purposes of compatibility and States should adopt this terminology consistently throughout their requirements.
	Lot Tolerance Percent Defective	B	
§32.3	Maintenance of records	D	
§32.8	Information collection requirements: OMB approval	D	
§32.11	Introduction of byproduct material in exempt concentrations into products or materials and transfer of ownership or possession: Requirements for license	C - paragraphs (a) and (b) B - paragraph (c)	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.12	Same: Records and material transfer reports	C	
§32.13	Same: Prohibition of introduction	C	
§32.14	Certain items containing byproduct material; requirements for license to apply or initially transfer	NRC	
§32.15	Same: Quality assurance, prohibition of transfer and labeling	NRC	
§32.16	Certain items containing byproduct material: Records and reports of transfer	NRC	
§32.17	Resins containing scandium-46 and designed for sand-consolidations in oil wells: Requirements for license to manufacture, or initially transfer for sale or distribution	B	This provision was previously designated as an area reserved to the NRC. A review of the Statements of Considerations for this rule (32 FR 4241, 3/18/67) indicates that this activity can be licensed by an Agreement State. The Commission considered that scandium-46 resins were not a product intended for use by the general public. Therefore, this authority could be assumed by the States.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.18	Manufacture, distribution and transfer of exempt quantities: Requirements for license	NRC	
§32.19	Same: Conditions of licenses	NRC	
§32.20	Same: Records and material transfer reports	NRC	
§32.22	Self luminous products containing tritium, krypton-85 and promethium-147: Requirements for license to manufacture, process, produce, or initially transfer:	NRC	
§32.23	Same: Safety criteria	NRC	
§32.24	Same: Table of organ doses	B	See 10 CFR § 32.51. This table should be adopted in essentially identical language since §32.51 should be so adopted. The table may be incorporated with the Agreement State's requirements which are equivalent to §32.51, as appropriate, rather then referenced separately.
§32.25	Conditions of licenses issued under §32.22: Quality Control, labeling and reports of transfer	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.26	Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce or initially transfer	NRC	
§32.27	Same: Safety criteria	NRC	
§32.28	Same: Table of organ doses	NRC	
§32.29	Conditions of licenses issued under §32.26: Quality control, labeling and reports of transfer	NRC	
§32.40	Schedule A: Prototype tests for automobile lock illuminators	NRC	
§32.51	Byproduct material contained in devices for use under §31.5: Requirements for license to manufacture or initially transfer	B	
§32.51a	Same: Conditions of licenses	B	
§32.52	Same: Material transfer reports and records	B	
§32.53	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.54	Same: Labeling of devices	B	
§32.55	Same: Quality assurance; prohibition of transfer	B	
§32.56	Same: Material transfer reports	B	
§32.57	Calibration or reference sources Am-241: Requirements for license to manufacture or initially transfer	B	
§32.58	Same: Labeling of devices	B	
§32.59	Same: Leak testing of each source	B	
§32.60	[Reserved]		
§32.61	Ice detection devices containing strontium-90; Requirements for license to manufacture or initially transfer	B	
§32.62	Same: Quality Assurance; prohibition of transfer	B	
§32.71	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§32.72	Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35	B	
§32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use	B	
§32.101	Schedule B-prototype tests for luminous safety devices for use in aircraft	B	
§32.102	Schedule C-prototype tests for calibration or reference sources containing americium-241	B	
§32.103	Schedule D-prototype tests for ice detection devices containing strontium 90	B	
§32.110	Acceptance sampling procedures under specific licenses	B	
§32.210	Registration of product information	B	
§32.301	Violations	D	
§32.303	Criminal penalties	D	

Part 33 - SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§33.1	Purpose and scope	D	
§33.8	Information collection requirements: OMB approval	D	
§33.11	Types of specific licneses of broad scope	D	
§33.12	Applications for specific licenses of broad scope	D	
§33.13	Requirements for the issuance of a Type A specific license of broad scope	D	
§33.14	Requirements for the issuance of a Type B specific license of broad scope	D	
§33.15	Requirements for the issuance of a Type C specific license of broad scope	D	
§33.16	Application for other specific licenses	D	
§33.17	Conditions of specific licenses of broad scope	D	
§33.21	Violations	D	

§33.23	Criminal penalties	D	
§33.100	Schedule A	D	

Part 34 - LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§34.1	Purpose and Scope	D	
§34.2	Definitions		
	Permanent radiographic installation	D	
	Radiographer	C	
	Radiographer's assistant	D	
	Radiographic exposure device	B	
	Radiography	B	
	Sealed source	[A]	This definition also appears in 10CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category A.
	Source changer	B	
	Storage area	D	
	Storage container	B	
§34.3	Applications for specific licenses	D	
§34.4	Maintenance of records	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§34.8	Information collection requirements: OMB approval	D	
§34.11	Issuance of specific licenses for use of sealed sources in Industrial Radiography	C	
§34.20	Performance requirements for radiography equipment	B	
§34.21	Limits on levels of radiation for radiographic exposure devices and storage containers	B	
§34.22	Locking of radiographic exposure devices, storage containers and source changers	B	
§34.23	Storage precautions	C	
§34.24	Radiation survey instruments	C	
§34.25	Leak testing, repair, tagging, opening, modification, and replacement of sealed sources	C	
§34.26	Quarterly Inventory	C	
§34.27	Utilization logs	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§34.28	Inspection and maintenance of radiographic exposure devices, storage containers, and source changers	C	
§34.29	Permanent Radiographic Installations	D	H&S
§34.30	Reporting requirements	C	
§34.31	Training	C	
§34.32	Operating and Emergency procedures	C - paragraphs (a) through (k) D - paragraph (l)	
§34.33	Personnel monitoring	C	
§34.41	Security	C	
§34.42	Posting	C	
§34.43	Radiation surveys	C - paragraphs (a), (b) and (c) D - paragraph (d)	
§34.44	Supervision of radiographers' assistant	D	
§34.51	Applications for exemptions	D	
§34.61	Violations	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§34.63	Criminal Penalties	D	
Appendix A	Required subjects for training instruction	C	

Part 35 - MEDICAL USE OF BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.1	Purpose and scope	D	
§35.2	Definitions		
	Address of use	D	
	ALARA	[A]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category A.
	Agreement State	[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.
	Area of use	D	
	Authorized nuclear pharmacist	D	
	Authorized user	C	
	Brachytherapy source	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Dedicated check source	D	
	Dental use	D	
	Dentist	D	
	Diagnostic clinical procedures manual	D	
	Management	D	
	Medical institution	D	
	Medical use	C	
	Ministerial change	D	
	Misadministration	C	States should adopt the quantitative values (e.g. the % differences; dose equivalents) in this provision in order to meet the essential objectives of this requirement
	Mobile nuclear medicine service	D	
	Output	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Pharmacist	D	
	Physician	D	
	Podiatric use	D	
	Podiatrist	D	
	Prescribed dosage	C	
	Prescribed dose	C	
	Radiation safety officer	D	
	Recordable event	D	
	Sealed source	[B]	This definition also appears in 10CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.
	Teletherapy physicist	D	
	Written directive	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.5	Maintenance of records	D	
§35.6	Provisions for research involving human subjects.	D	
§35.7	FDA, other Federal, and State requirements	D	
§35.8	Information collection requirements: OMB Approval	D	
§35.11	License required	[C]	The general requirement for activities to be licensed appears in 10 CFR § 30.4 which has been designated compatibility category C. Agreement States should adopt the Part 30 provision as a minimum requirement for their licensees.
§35.12	Application of license, amendment, or renewal	D	
§35.13	License amendments	D	
§35.14	Notifications	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.15	Exemptions regarding Type A specific licenses of broad scope	D	
§35.18	License issuance	D	
§35.19	Specific exemptions	D	
§35.20	ALARA program	[D]	The provision for ALARA requirements appears in 10 CFR §20.1101(b) and is generally applicable to all licensees. This provision is not required for purposes of compatibility, but does have health and safety (H&S) significance.
§35.21	Radiation Safety Officer	D	H&S - paragraph (a) only
§35.22	Radiation safety committee	D	
§35.23	Statements of authority and responsibilities	D	H&S - paragraph (a) only
§35.25	Supervision	D	
§35.29	Administrative requirements that apply to the provision of mobile nuclear medicine service	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.31	Radiation safety program changes	D	
§35.32	Quality management program	D	H&S - paragraphs (a), (b) and (c)
§35.33	Notifications, reports, and records of misadministrations	C	
§35.49	Suppliers for sealed sources or devices for medical use	D	
§35.50	Possession, use, calibration, and check of dose calibrators	D	
§35.51	Calibration and check of survey instruments	[D]	The generally applicable provision for possession of calibrated survey instruments appears in 10 CFR §20.1501(b). It is not required for purposes of compatibility, but does have health and safety (H&S) significance.
§35.52	Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.53	Measurements of dosages of unsealed byproduct material for medical use	D	H&S - paragraphs (a) and (b) only
§35.57	Authorization of calibration and reference sources	D	
§35.59	Requirements for possession of sealed sources and brachytherapy sources	D	H&S
§35.60	Syringe shields and labels	D	
§35.61	Vial shields and labels	D	
§35.70	Surveys for contamination and ambient radiation exposure rate	D	H&S
§35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.80	Technical requirements that apply to the provision of mobile nuclear medicine services	D	
§35.90	Storage of volatiles and gases	D	
§35.92	Decay-in-storage	D	
§35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies	D	H&S
§35.120	Possession of survey instruments	D	
§35.200	Use of unsealed byproduct material for imaging and localization studies	D	H&S
§35.204	Permissible molybdenum-99 concentration	D	H&S

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.205	Control of aerosols and gases	[D]	10 CFR §20.1201 and §20.1301 specify occupational and public dose limits, respectively, and are designated compatibility category A. Since this section directly references the Part 20 sections, it is not required for purposes of compatibility.
§35.220	Possession of survey instruments	[D]	The generally applicable provision for possession of calibrated survey instruments appears in 10 CFR §20.1501(b). It is not required for purposes of compatibility, but does have health and safety (H&S) significance.
§35.300	Use of unsealed byproduct material for therapeutic administration	D	H&S
§35.310	Safety instruction	D	
§35.315	Safety precautions	D	
§35.320	Possession of survey instruments	D	
§35.400	Use of sources for brachytherapy	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.404	Release of patients or human research subjects treated with temporary implants	C	
§35.406	Brachytherapy sources inventory	D	H&S - paragraphs (a) and (c) only
§35.410	Safety instruction	D	
§35.415	Safety precautions	D	
§35.420	Possession of survey instruments	D	
§35.500	Use of sealed sources for diagnosis	D	
§35.520	Availability of survey instrument	D	
§35.600	Use of a sealed source in a teletherapy unit	D	
§35.605	Maintenance and repair restrictions	D	H&S
§35.606	License amendments	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.610	Safety instructions	D	H&S
§35.615	Safety precautions	D	H&S
§35.620	Possession of survey instrument	D	
§35.630	Dosimetry equipment	D	H&S
§35.632	Full calibration measurements	D	States should adopt the quantitative values (e.g. % output differences and the times of calibrations) in this provision in order to meet the essential objectives of this requirement. H&S
§35.634	Periodic spot-checks	D	H&S
§35.636	Safety checks for teletherapy facilities	D	H&S
§35.641	Radiation surveys for teletherapy facilities	D	
§35.643	Modification of teletherapy unit or room before beginning a treatment program	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.645	Reports of teletherapy surveys, checks, tests, and measurements	D	
§35.647	Five-year inspection	D	H&S
§35.900	Radiation safety officer	D	
§35.901	Training for experienced radiation safety officer	D	
§35.910	Training for uptake, dilution, and excretion studies	D	
§35.920	Training for imaging and localization studies	D	
§35.930	Training for therapeutic use of unsealed byproduct material	D	
§35.932	Training for treatment of hyperthyroidism	D	
§35.934	Training for thyroid carcinoma	D	
§35.940	Training for use of brachytherapy sources	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.941	Training for ophthalmic use of strontium-90	D	
§35.950	Training for use of sealed sources for diagnosis	D	
§35.960	Training for teletherapy	D	
§35.961	Training for teletherapy physicist	D	
§35.970	Training for experienced authorized users	D	
§35.971	Physician training in a three month program	D	
§35.972	Recentness of training	D	
§35.980	Training for an authorized nuclear pharmacist	D	
§35.981	Training for experienced nuclear pharmacist	D	
§35.990	Violations	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.991	Criminal penalties	D	
§35.999	Resolution of conflicting requirements during transition period	D	

Part 36 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§36.1	Purpose & Scope	D - paragraph (a) C - paragraphs (b) and (c)	States should adopt the quantitative values and irradiator types in paragraphs (b) and (c) to meet the essential objectives of this requirement in order to avoid potential conflicts between jurisdictions.
§36.2	Definitions		
	Annually	D	
	Doubly encapsulated sealed source	D	
	Irradiator	C	
	Irradiator operator	D	
	Panoramic dry-source-storage irradiator	D	
	Panoramic irradiator	D	
	Panoramic wet-source-storage irradiator	D	
	Pool irradiator	D	
	Product conveyor system	D	
	Radiation room	D	
	Radiation safety officer	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Sealed source	[B]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.
	Seismic area	D	
	Underwater irradiator	D	
§36.5	Interpretations	D	
§36.8	Information collection requirements: OMB approval	D	
§36.11	Application for a specific license	D	
§36.13	Specific licenses for irradiators	D	H&S
§36.15	Start of construction	D	
§36.17	Applications for exemptions	D	
§36.19	Request for written statements	D	
§36.21	Performance criteria for sealed sources	B	States should adopt the quantitative values and types of tests in this provision to meet the essential objectives of this requirement.
§36.23	Access control	D	H&S

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§36.25	Shielding	D	H&S
§36.27	Fire protection	D	H&S
§36.29	Radiation monitors	D	H&S
§36.31	Control of source movement	D	H&S
§36.33	Irradiator pools	D	H&S
§36.35	Source rack protection	D	
§36.37	Power failures	D	H&S
§36.39	Design requirements	D	H&S
§36.41	Construction monitoring and acceptance testing	D	H&S
§36.51	Training	D	H&S
§36.53	Operating & Emergency procedures	D	H&S
§36.55	Personnel monitoring	D	
§36.57	Radiation surveys	D	H&S States should adopt the quantitative values for surveys in this provision to meet the essential objectives of this requirement.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§36.59	Detection of leaking sources	D	H&S States should adopt the quantitative values for detection of leaking sources in this provision to meet the essential objectives of this requirement.
§36.61	Inspection and maintenance	D	H&S
§36.63	Pool water purity	D	H&S States should adopt the quantitative values for pool water purity in this provision to meet the essential objectives of this requirement.
§36.65	Attendance during operation	D	H&S
§36.67	Entering and leaving the radiation room	D	H&S
§36.69	Irradiation of explosive or inflammable materials	D	H&S
§36.81	Records and retention periods	D	
§36.83	Reports	C	
§36.91	Violations	D	
§36.93	Criminal penalties	D	

Part 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§39.1	Purpose and Scope	D	
§39.2	Definitions		
	Field station	B	
	Fresh water aquifer	D	
	Injection tool	D	
	Irretrievable well logging source	D	
	Licensed material	D	
	Logging assistant	D	
	Logging supervisor	C	
	Logging tool	D	
	Personal supervision	D	
	Radioactive marker	D	
	Safety review	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Sealed source	[B]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.
	Source holder	D	
	Subsurface tracer study	D	
	Surface casting for protecting fresh water aquifiers	D	
	Temporary jobsite	D	
	Uranium sinker bar	D	
	Well	D	
	Well logging	C	
§39.5	Interpretations	D	
§39.8	Information collection requirements: OMB approval	D	
§39.11	Application for a specific license	D	
§39.13	Specific licenses for well logging	D	H&S

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§39.15	Agreement with well owner or operator	C	
§39.17	Request for written statements	D	
§39.31	Labels, security, and transportation precautions	D - paragraph (a) C - paragraph (b)	
§39.33	Radiation detection instruments	C - paragraphs (a) and (c) D - paragraphs (b) and (d)	H&S - paragraph (b)
§39.35	Leak testing of sealed sources	C	
§39.37	Physical inventory	D	H&S
§39.39	Records of material use	C	
§39.41	Design and performance criteria for sealed sources	B	
§39.43	Inspection, maintenance, and opening of a source or source holder	C	
§39.45	Subsurface tracer studies	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§39.47	Radioactive markers	D	
§39.49	Uranium sinker bars	C	
§39.51	Use of sealed source in a well without surface casing	D	
§39.61	Training	C	The essential objectives of these provisions should be adopted by States because they contain training requirements specific to well logging not contained in 10 CFR §19.12 and apply to persons who frequently work in multiple jurisdictions.
§39.63	Operating & Emergency procedures	C	
§39.65	Personnel monitoring	C - paragraph (a) D - paragraphs (b) and (c)	
§39.67	Radiation surveys	C	
§39.69	Radioactive contamination control	C	
§39.71	Security	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§39.73	Documents & records required at field stations	C	
§39.75	Documents & records required at temporary job sites	C	
§39.77	Notification of incidents: abandonment procedures for irretrievable sources	C - paragraphs (a), (c) and (d) D - paragraph (b)	
§39.91	Applications for exemptions	D	
§39.101	Violations	D	
§39.103	Criminal penalties	D	

Part 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.1	Purpose	D	
§40.2	Scope	D	
§40.2a	Coverage of inactive tailings sites	A - States with authority to regulate uranium mill activities (11.e.2 byproduct material) D - States without authority	
§40.3	License requirements	C	
§40.4	Definitions		
	Act	D	
	Agreement State	[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Alert	[A]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category A.
	Byproduct material	[A]	This definition also appears in 10 CFR §150.3(c). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Commencement of construction	[D]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category D.
	Commission	D	
	Decommission	[C]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category C.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Department of Energy	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Depleted uranium	A	
	Effective kilogram	D	
	Government agency	D	
	License	D	
	Persons	[C]	This definition also appears in 10 CFR §150.3(g). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category C.
	Pharmacist	[D]	This definition also appears in 10 CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category D.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Physician	[D]	This definition also appears in 10 CFR §35.2. For purposes of compatibility, the language of the Part 35 definition should be used and it is assigned to Compatibility Category D.
	Principle activities	[D]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category D.
	Residual radioactive material	A - States with authority to regulate uranium mill activities (11.e.2 byproduct material) D - States without authority	
	Site area emergency	[A]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category A.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Source material	[A]	This definition also appears in 10 CFR §150.3(i). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Special nuclear material	[A]	This definition also appears in 10 CFR §150.3(j). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Transient shipment	D	
	United States	D	
	Unrefined and unprocessed ore	B	
	Uranium enrichment facility	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Uranium milling	C - States with authority to regulate uranium mill activities (11.e.2 byproduct material) D - States without this authority	
§40.5	Communications	D	
§40.6	Interpretations	D	
§40.7	Employee protection	D	
§40.8	Information collection requirements: OMB approval	D	
§40.9	Completeness and accuracy of information	D	
§40.10	Deliberate misconduct	C	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.11	Persons using source material under certain Department of Energy and Nuclear Regulatory Commission contracts	B	
§40.12	Carriers	B	
§40.13	Unimportant quantities of source material	B	
§40.14	Specific exemptions	D - paragraph (a) NRC - paragraphs (c) and (d)	
§40.20	Types of licenses	D	
§40.21	General license to receive title to source or byproduct material	C	
§40.22	Small quantities of source material	B	
§40.23	General license for carriers of transient shipments of natural uranium other than in the form of ore or ore residue	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.25	General license for use of certain industrial products or devices	C	
§40.26	General license for possession and storage of byproduct material as defined in this part	C - States with authority to regulate uranium mill activities (11e.2 byproduct material) D - States without authority	
§40.27	General license for custody and long-term care of residual radioactive material disposal sites	NRC	
§40.28	General license for custody and long-term care of uranium or thorium byproduct materials disposal sites	NRC	
§40.31	Application for specific licenses	D	H&S - paragraph (i) only

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.32	General requirements for issuance of specific licenses	D - paragraphs (a) through (g) except NRC - paragraphs (d), (e) and (g)	H&S - paragraphs (b) and (c)
§40.33	Issuance of a license for a uranium enrichment facility	NRC	
§40.34	Special requirements for issuance of specific licenses	B - paragraphs (a)(2) and (a)(3) D - paragraphs (a)(1), (b) and (c)	
§40.35	Conditions of specific licenses issued pursuant to §40.34	B - paragraphs (b) and (c) C - paragraph (a) D - paragraphs (d), (e), and (f)	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.36	Financial assurance and recordkeeping for decommissioning	D	H&S - paragraphs (a),(b) and (d) only States have the flexibility to specify different dollar amounts based on jurisdiction and local conditions.
§40.41	Terms and conditions of licenses	D	
§40.42	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas	D	H&S - paragraphs (c), (d), (e), (g), (h), (j) and (k) only
§40.43	Renewal of licenses	D	
§40.44	Amendment of licenses at request of licensee	D	
§40.45	Commission action on application to renew or amend	D	
§40.46	Inalienability of licenses	C	
§40.51	Transfer of source or byproduct material	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.60	Reporting requirements	C - paragraphs (a), (b) and (c), except D - paragraph (c)(3)	
§40.61	Records	C - paragraphs (a) and (b) D - paragraph (c)	
§40.62	Inspections	D	
§40.63	Tests	D	
§40.64	Reports	NRC	
§40.65	Effluent monitoring reporting requirements	C - states with authority to regulate uranium mill activities (11e.2 byproduct material) D - states without authority	
§40.66	Requirements for advance notice of export shipments of natural uranium	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§40.67	Requirement for advance notice of importation of natural uranium from countries that are not party to the Convention on the Physical Protection of Nuclear Material	NRC	
§40.71	Modification and revocation of licenses	D	
§40.81	Violations	D	
§40.42	Criminal penalties	D	
APPENDIX A		C - states with authority to regulate uranium mill activities (11e.2 byproduct material) D - states without authority	

Part 61 - LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
§61.1	Purpose & Scope	D	
§61.2	Definitions		
	Active maintenance	D	H&S
	Buffer zone	D	
	Chelating agent	D	
	Commencement of construction	D	
	Commission	D	
	Custodial Agency	D	
	Director	D	
	Disposal	C	
	Disposal site	C	
	Disposal unit	D	
	Engineered barrier	D	
	Explosive material	D	
	Government agency	D	
	Hazardous waste	C	
	Hydrogeologic unit	D	
	Inadvertent intruder	C	

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
	Indian Tribe	D	
	Intruder barrier	C	
	Land disposal facility	D	
	License	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Monitoring	C	
	Near-surface disposal facility	D	
	Person	[C]	This definition also appears in 10 CFR §150.3(g). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category C.
	Pyrophoric liquid	D	
	Site closure and stabilization	D	
	State	D	
	Stability	D	
	Surveillance	D	

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
	Tribal governing body	D	
	Waste	B	
§61.3	License required	C	
§61.4	Communications	D	
§61.5	Interpretations	D	
§61.6	Exemptions	D	
§61.7	Concepts	D	H&S
§61.8	Information collection requirements: QMB approval	D	
§61.9	Employee protection	D	
§61.9a	Completeness and accuracy of information	D	
§61.9b	Deliberate misconduct	D	
§61.10	Content of application	D	
§61.11	General information	D	
§61.12	Specific technical information	D	
§61.13	Technical analysis	D	H&S
§61.14	Institutional information	D	H&S
§61.15	Financial information	D	

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
§61.16	Other information	NRC	
§61.20	Filing and distribution of application	D	
§61.21	Elimination of repetition	D	
§61.22	Updating of application	D	
§61.23	Standards for issuance of a license	D - paragraphs (a) through (h), (k) and (l) NRC - paragraphs (i) and (j)	H&S - paragraphs (a) through (h)
§61.24	Conditions of licenses	D	
§61.25	Changes	D	
§61.26	Amendment of license	D	
§61.27	Application for renewal or closure	D	
§61.28	Contents of application for closure	D	
§61.29	Post-closure observation and maintenance	D	
§61.30	Transfer of license	D	
§61.31	Termination of license	D	
§61.40	General requirement	D	

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
§61.41	Protection of the general population from releases of radioactivity	A	
§61.42	Protection of individuals from inadvertent intrusion	D	H&S
§61.43	Protection of individuals during operations	D	Covered by provisions in Part 20
§61.44	Stability of the disposal site after closure	D	H&S
§61.50	Disposal site suitability requirements for land disposal	D	H&S
§61.51	Disposal site design for land disposal	D	H&S
§61.52	Land disposal facility operation and disposal site closure	D	H&S
§61.53	Environmental monitoring	D	H&S
§61.54	Alternative requirements for design and operations	D	H&S
§61.55	Waste classification	B	
§61.56	Waste characteristics	D	H&S

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
§61.57	Labeling	D	H&S States should adopt this provision for safety to prevent overexposure from mishandling of wastes with high activities.
§61.58	Alternative requirements for waste classification and characteristics	D	
§61.59	Institutional requirements	D	H&S
§61.61	Applicant qualifications and assurances	D	
§61.62	Funding for disposal site closure and stabilization	D	H&S
§61.63	Financial assurances for institutional controls	D	H&S
§61.70	Scope	D	
§61.71	State and Tribal government consultation	D	
§61.72	Filing of proposals for State and Tribal participation	D	
§61.73	Commission approval of proposals	D	
§61.80	Maintenance of records, reports, and transfers	C	

REGULATION SECTION	SECTION TITLE	COMAPTIBILITY CATEGORY	COMMENTS
§61.81	Tests at land disposal facilities	D	
§61.82	Commission inspections of land disposal facilities	D	
§61.83	Violations	D	
§61.84	Criminal penalties	D	

Part 70 - DOMSTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.1	Purpose	D	
§70.2	Scope	D	
§70.3	License requirements	C	
§70.4	Definitions		
	Act	D	
	Agreement State	[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.
	Alert	[A]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category A.
	Atomic Energy	D	
	Atomic Weapon	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Commencement of construction	[D]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category D.
	Commission	D	
	Common defense and security	D	
	Contiguous sites	D	
	Decommission	[C]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category C.
	Department or Department of Energy	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Effective dose equivalent	[A]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category A.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Effective kilograms of special nuclear material	D	
	Formula quantity	D	
	Government agency	D	
	License	[D]	This definition also appears in 10 CFR §20.1003. For purposes of compatibility, the language of the Part 20 definition should be used and it is assigned to Compatibility Category D.
	Persons	[C]	This definition also appears in 10 CFR §150.3(g). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category C.
	Plutonium processing and fuel fabrication plant	D	
	Principal activities	[D]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category D.
	Produce	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Research and development	D	
	Restricted data	D	
	Sealed source	[B]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.
	Site area emergency	[A]	This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category A.
	Source material	[A]	This definition also appears in 10 CFR §150.3(i). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Special nuclear material	[A]	This definition also appears in 10 CFR §150.3(j). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category A.
	Special nuclear material of low strategic significance	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Special nuclear material of moderate strategic significance	NRC	
	Special nuclear material scrap	D	
	Strategic special nuclear material	NRC	
	Transient shipment	NRC	
	United States	NRC	
	Uranium enrichment facility	NRC	
§70.5	Communications	D	
§70.6	Interpretations	D	
§70.7	Employee protection	D	
§70.8	Information collection requirements; OMB approval	D	
§70.9	Completeness and accuracy of information	D	
§70.10	Deliberate misconduct	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.11	Persons using special nuclear material under certain DOE and NRC contracts	B	
§70.12	Carriers	B	
§70.13	Department of Defense	NRC	
§70.13a	Foreign military aircraft	NRC	
§70.14	Specific exemption	D	
§70.18	Types of licenses	D	
§70.19	General license for calibration or reference sources	C	
§70.20	General license to own special nuclear material	C	
§70.20a	General license to possess special nuclear material for transport	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.20b	General license for carriers of transient shipments of formula quantities of strategic special nuclear material, special nuclear material of moderate strategic significance, special nuclear material of low strategic significance, and irradiated reactor fuel	NRC	
§70.21	Filing	C - paragraphs (a)(1), (a)(2), (a)(3), (b) and (d) D - paragraph (e) NRC - paragraphs (c), (f), (g), and (h)	
§70.22	Contents of application	D - paragraphs (a), (d) and (e) NRC - paragraphs (b), (c), (f), (g), (h), (i), (j), (k), (l), (m), and (n)	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.23	Requirements for the approval of applications	D - paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), and (a)(6) NRC - paragraphs (a)(7), (a)(8), (a)(9), (a)(10), (a)(11), and (a)(12)	
§70.23a	Hearing required for uranium enrichment facility	NRC	
§70.24	Critically accident requirements	NRC	
§70.25	Financial assurance and recordkeeping for decommissioning	D	H&S - paragraphs (a), (b) and (d) only States have the flexibility to specify different dollar amounts based on jurisdiction and local conditions
§70.31	Issuance of licenses	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.32	Conditions of licenses	D - paragraphs (a)(2), (a)(3), (a)(8), and (a)(9) NRC - paragraphs (a)(1), (a)(4), (a)(5), (a)(6), (a)(7), (b)(1), (b)(2), (b)(3), (b)(4), (b)(5), (c), (d), (e), (f), (g), (h), (i), (j) and (k)	
§70.33	Renewal of licenses	D	
§70.34	Amendment of licenses	D	
§70.35	Commission action on applications to renew or amend	D	
§70.36	Inalienability of licenses	C	
§70.37	Disclaimer of warranties	NRC	
§70.38	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas	D	H&S - paragraphs (c), (d), (e), (g), (h), (j) and (k) only

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.39	Specific licenses for the manufacture or initial transfer of calibration sources	C	
§70.41	Authorized use of special nuclear material	D	
§70.42	Transfer of special nuclear material	B	
§70.44	Creditor regulations	NRC	
§70.50	Reporting requirements	C - paragraphs (a), (b) and (c), except D - paragraph (c)(3)	
§70.51	Material balance, inventory, and records requirements	NRC	
§70.52	Reports of accidental critically or loss or theft or attempted theft of special nuclear material	NRC	
§70.53	Material status reports	NRC	
§70.54	Nuclear material transfer reports	NRC	
§70.55	Inspections	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§70.56	Tests	NRC	
§70.57	Measurement control program for special nuclear material accounting and control	NRC	
§70.58	Fundamental nuclear material controls	NRC	
§70.59	Effluent monitoring reporting requirements	NRC	
§70.61	Modification and revocation of licenses	D	
§70.62	Suspension and operation in war or national emergency	NRC	
§70.71	Violations	D	
§70.72	Criminal penalties	D	

Part 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.0	Purpose and Scope	D	
§71.1	Communications and Records	D	
§71.2	Interpretations	D	
§71.3.	Requirements for license	D	
§71.4	Definitions		
	A_1	B	
	Carrier	B	
	Certificate holder	B	
	Close reflection by water	NRC	
	Containment System	B	
	Conveyance		
	Exclusive use	B	
	Fissile material	B	
	Licensed material	B	
	Low Specific Activity (LSA) material	B	
	Low toxicity alpha emitters	B	
	Maximum normal operating pressure	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Natural thorium	B	
	Normal form radioactive material	B	
	Optimum interspersed hydrogenous moderation	NRC	
	Package	B	
	Fissile material package	B	
	Type B package	B	
	Packaging	B	
	Special form radioactive material	B	
	Specific activity	B	
	State	D	
	Surface Contaminated Object (SCO)	B	
	Transport Index	B	
	Type A quantity	B	
	Type B quantity	B	
	Natural Uranium	B	
	Depleted Uranium	B	
	Enriched Uranium	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.5	Transportation of Licensed Material	B	
§71.6	Information collection requirements: OMB approval	D	
§71.7	Completeness and accuracy of Information	D	
§71.8	Specific exemptions	D	
§71.9	Exemption for physicians	D	
§71.10	Exemptions for low level material	B	
§71.12	General license: NRC-approved package	B	
§71.13.	Previously approved package	B	
§71.14	General license: DOT specification container material	B	
§71.16	General license: Use of foreign approved package	B	
§71.18	General license: Fissile material, limited quantity of package	D	This provision is not required for purposes of compatibility. However, if a State chooses to adopt such a provision and issue the GL, the provisions should be essentially identical to those of NRC.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.20	General license: Fissile material, limited moderator per package	D	This provision is not required for purposes of compatibility. However, if a State chooses to adopt such a provision and issue the GL, the provisions should be essentially identical to those of NRC.
§71.22	General license: Fissile material, limited quantity, Controlled Shipment	D	This provision is not required for purposes of compatibility. However, if a State chooses to adopt such a provision and issue the GL, the provisions should be essentially identical to those of NRC.
§71.24	General license: Fissile material, limited moderator, controlled shipment	NRC	
§71.31	Contents of Application	NRC	
§71.33	Package description	NRC	
§71.35	Package evaluation	NRC	
§71.37	Quality Assurance	NRC	
§71.39	Requirements for additional information	NRC	
§71.41	Demonstration of Compliance	NRC	
§71.43	General Standards for all packages	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.45	Lifting and tie-down Standards for all packages	NRC	
§71.47	External radiation Standards for all packages	NRC	
§71.51	Additional Requirements for Type B packages	NRC	
§71.52	Exemption for low-specific-activity (LSA) packages	NRC	
§71.53	Fissile material exemptions	NRC	
§71.55	General Requirements for fissile material packages	NRC	
§71.57	Reserved		
§71.59	Standards for arrays of fissile material packages	NRC	
§71.61	Special requirements for irradiated nuclear fuel shipments	NRC	
§71.63	Special requirements for plutonium shipments	NRC	
§71.64	Special requirements for plutonium air shipments	NRC	
§71.65	Additional Requirements	NRC	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.71	Normal conditions of transport	NRC	
§71.73	Hypothetical accident conditions	NRC	
§71.74	Accident conditions for air transport of plutonium	NRC	
§71.75	Qualification of special form radioactive material	NRC	
§71.77	Qualification of LSA-III material	NRC	
§71.81	Applicability of operating controls	B	
§71.83	Assumptions as to unknown properties	NRC	
§71.85	Preliminary determinations	B	
§71.87	Routine determinations	B	
§71.88	Air Transportation of plutonium	B	
§71.89	Opening instructions	B	
§71.91	Records	D	
§71.93.	Inspection and tests	D	
§71.95	Reports	D	
§71.97	Advance notification of shipment of irradiated reactor fuel and nuclear waste	B	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.99	Violations	D	
§71.100	Criminal penalties	D	
§71.101	Quality assurance requirements	D	
§71.103	Quality assurance organization	D	
§71.105	Quality assurance program	D	
§71.107	Package design control	D	
§71.109	Procurement document control	D	
§71.111	Instructions, procedures, and drawings	D	
§71.113	Document control	D	
§71.115	Control of purchased material, equipment, and services	D	
§71.117	Identification and control of materials, parts, and components	D	
§71.119	Control of special processes	D	
§71.121	Internal Inspection	D	
§71.123	Test control	D	
§71.125	Control of measuring and test equipment	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§71.127	Handling, storage, and shipping control	D	
§71.129	Inspection, test, and operating status	D	
§71.131	Nonconforming materials, parts, or components	D	
71.133	Corrective action	D	
§71.135	Quality assurance records	D	
§71.137	Audits	D	
Appendix A	Determination of A1 and A2	B	

Part 150 - EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§150.1	Purpose	D	
§150.2	Scope	D	
§150.3	Definitions		
§150.3(a)	Act	D	
§150.3(b)	Agreement State	B	Definition has significant nationwide and transboundary implications.
§150.3(c)	Byproduct Material	A	
§150.3(d)	Commission	D	
§150.3(e)	Government Agency	D	
§150.3(f)	Offshore Waters	B	Essential to the reciprocity provisions in §150.20
§150.3(g)	Person	C	
§150.3(h)	Production facility	NRC	Such facilities are outside Agreement State jurisdiction; however, if State chooses to define the term then the definition should be essentially identical.
§150.3(i)	Source material	A	
§150.3(j)	Special nuclear material	A	
§150.3(k)	State	D	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§150.3(l)	Utilization facility	NRC	Such facilities are outside Agreement State jurisdiction; however, if State chooses to define the term then the definition should be essentially identical.
§150.3(m)	Uranium enrichment facility	NRC	Such facilities are outside Agreement State jurisdiction; however, if State chooses to define the term then the definition should be essentially identical.
§150.4	Communications	D	
§150.5	Interpretations	D	
§150.7	Persons in offshore waters not exempt	NRC	
§150.8	Information collection requirements: OMB approval	D	
§150.10	Persons exempt	NRC	Exemption addresses discontinuance of NRC authority in an Agreement State
§150.11	Critical mass	B	Defines scope of authority that NRC can relinquish to States for special nuclear materials. This must be identical from State to State and therefore has significant and direct transboundary implications.
§150.14	Commission regulatory authority for physical protection	NRC	Provision addresses continuing NRC authority over special nuclear material.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§150.15	Persons not exempt	NRC	Provision addresses continuing NRC authority over certain activities in Agreement States.
§150.15a	Continued Commission authority pertaining to byproduct material	NRC	Provision addresses continuing NRC authority over certain activities in Agreement States.
§150.16	Submission to Commission of nuclear material transfer reports	NRC	Although an issue within NRC exclusive jurisdiction, States should adopt some method to advise their licensees of these NRC requirements.
§150.17	Submission to Commission of source material reports	NRC	Although an issue within NRC exclusive jurisdiction, States should adopt some method to advise their licensees of these NRC requirements.
§150.17a	Compliance with requirements of US/IAEA safeguards agreement	NRC	
§150.19	Submission to Commission of tritium reports	NRC	Although an issue within NRC exclusive jurisdiction, States should adopt some method to advise their licensees of these NRC requirements.
§150.20	Recognition of Agreement State licenses	C - paragraphs (a) and (b) NRC - paragraphs (c) and (d)	Provisions in (a) and (b) are important for coherent regulation of agreement material on a national basis. Provisions in (c) & (d) relate to NRC authority to regulate activities in offshore waters.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§150.21	Transportation of special nuclear material by aircraft	NRC	Provision addresses continuing NRC authority over activities in Agreement States
§150.30	Violations	D	
§150.31	Requirements for Agreement State regulation of byproduct material	C - States with authority to regulate uranium mill activities (11e.2 byproduct material) D - States without authority	
§150.32	Funds for reclamation or maintenance of byproduct material	C - States with authority to regulate uranium mill activities (11e.2 byproduct material) D - States without authority	
§150.33	Criminal penalties	D	

PROGRAM ELEMENTS

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
Legislation and Legal Authority	Adequacy	See discussion in Adequacy Section of Policy Statement
-- Regulations	See Classification Tables for 10 CFR parts in OSP Internal Procedure B.7 (Rev. 1)	
-- Guidance documents and interpretations	D	
Licensing	Adequacy	See discussion in Adequacy Section of Policy Statement
-- Reciprocal recognition of licenses	C	This program element has significant effects on the regulation of agreement material on a national basis. However, States should be provided flexibility for the type of license and time period recognized under reciprocity. Although there are transboundary implications, there is not a necessity for all States to be identical, such as would be required by a classification of "B."
-- Written procedures	C	
-- Maintenance of records, especially for decommissioning	C	
-- Inspection and licensing files	C	
Inspection and Enforcement	Adequacy	See discussion in Adequacy Section of Policy Statement
-- Written procedures	C	
-- Radiological laboratory support	D	
-- Instrumentation	D	
Personnel	Adequacy	See discussion in Adequacy Section of Policy Statement

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
-- Qualification procedures	C	There should be minimum education and experience requirements for all technical personnel in RCPs nationwide. Flexibility is provided to allow for different state administrative requirements.
Response to Events and Allegations	Adequacy	See discussion in Adequacy Section of Policy Statement
-- Written procedures	C	
-- Major incident investigation procedures	C	Need to prevent gaps in reporting effectiveness of national program
-- Procedures for investigation of "wrongdoing"	C	
Sealed source and device program	Adequacy	Non-common performance indicator
-- Standard review plan	C	
-- Format and content of registration certificates	B	Need to have national consistency so that all RCPs can rely on the specific information included in these documents.
-- Written procedures	C	
Low level waste	Adequacy	Non-common performance indicator.
-- Written procedures	C	
Uranium recovery	Adequacy	Non-common performance indicator.
-- Written procedures	C	
Exchange of information	C	Necessary for effective regulation of agreement material on a national basis; necessary for effective review of NRC and Agreement State programs for agreement material with respect to protection of public health and safety.
-- Event reporting	C	See previous comment.
Legal assistance	D	
Technical advisory committees	D	
Technical assistance and support	D	

PROGRAM ELEMENT	REQUIRED FOR	COMMENTS
Program funding, including program support services	D	
Organization, management & location of radiation control program	D	

ATTACHMENT 7

MY DISSENTING RECOMMENDATIONS
by John Telford

The Working Group has voted to classify § 35.32, The Quality Management Rule, as compatibility category D (i.e., not required for Agreement State licensees). The reasons for this vote seem to stem from a desire for State autonomy, lack of familiarity with the details of Part 35, reliance on rationale that I am not comfortable with, or some combination of these. First, because my views differ from those of the Working Group regarding the compatibility classification of § 35.32, I would like to offer three alternative recommendations, to be considered sequentially, and the rationale for each. Then, to address the bigger picture, I would like to offer two recommendations for the Commission's consideration as possible conclusive solutions in the medical use area.

1. Consider whether § 35.32 should be classified as compatibility category A because it establishes basic radiation protection standards.

Does § 35.32, like Part 20, establish **dose limits** which are basic radiation protection standards?

Recall that the regulatory limits established in Part 20 are, in part, to conduct licensee operations so that (1) no worker receives more than 5 rems per year (§ 20.1201) and (2) no member of the public receives more than 0.1 rem per year (§ 20.1301).

Consider that the regulatory limits established in § 35.32 are, paraphrased, to conduct medical use licensee operations so that no patient receives a therapy dose or dosage that is not as directed by the authorized user. Also consider (e.g., teletherapy) that specific dose limits are established by a chain of requirements: (1) the written directive required by § 35.32 for a teletherapy dose; (2) the definition, in § 35.2, of a written directive for teletherapy that requires the authorized user to specify: (a) the total dose, (b) dose per fraction, (c) treatment site, (d) and overall treatment period; and (3) the definition, also in § 35.2, of a teletherapy misadministration that specifies the dose limits are: (a) 10 percent of the total prescribed dose when the treatment consists of three or fewer fractions, (b) 30 percent of the weekly prescribed dose, and (c) 20 percent of the total prescribed dose (for greater than three fractions). Thus, for a teletherapy prescribed total dose of 5000 rads, with 200 rads per fraction, to be delivered in 25 fractions over a 5 week period the regulatory **dose limits** are 300 rads for the weekly dose and 1000 rads for the total dose. Of course, for any therapy administration the same chain of requirements will provide the dose limits when the written directive is completed. In addition, for misadministration (6) the **dose limits** of 5 rems effective dose equivalent to an individual or 50 rems dose equivalent to any individual organ are provided directly in the definition.

Therefore, like §§ 20.1201 and 20.1301, §§ 35.2 and 35.32 establish dose limits which are basic radiation protection standards. The former protects workers and members of the public from specified overdoses, while the latter protects patients receiving therapy doses of radiation from large overdoses, morbidity, and mortality.

Without § 35.32, would the Commission have basic radiation protection standards for patients receiving therapy doses of radiation in Agreement States? The answer

is no. Also without § 35.32, the Commission would be establishing radiation protection standards in Part 20 that focus on 5 rems per year (which has no immediate consequences), but not focusing any regulatory oversight on large patient overdoses, morbidity, or mortality. This would be an incongruous result.

Clearly the Commission attached a prominent level of importance to § 35.32 when it promulgated the Quality Management Rule in 1991, because it stated in Section V. "Implementation Plan and Agreement State Compatibility" of the Federal Register Notice that "...this amendment has safety significance for the Agreement State licensees as well as the NRC licensees,..." and "Additionally, the Commission believes that §§ 35.32 and 35.33 ... are necessary to ensure adequate protection of the public health and safety." (56 FR 34118)

This means that the compatibility category for § 35.32 and selected definitions in § 35.2 should be A. This also means that the Policy Statement should be changed in the Section on Compatibility, the first sentence under Basic Radiation Protection Standards, as follows; "For purposes of this Policy Statement, the term "basic radiation protection standards" means dose limits, concentration and release limits related to radiation protection in 10 CFR Part 20 that are generally applicable, and the dose limits established by 10 CFR 35.32 and 61.412."

2. Consider whether § 35.32 should be classified as compatibility category C because it is necessary to make effective the definition of misadministration and the associated misadministration reporting requirements for Agreement State licensees.

Consider the effects of classifying (as the Working Group has done) as compatibility category C the definitions for misadministration, prescribed dose and dosage, written directive, and the misadministration reporting requirements, but classifying § 35.32 as compatibility category D.

Recall that the definitions of misadministration, covering the various treatment modalities, depend on the definition, in § 35.2, of prescribed dose (or prescribed dosage), which in turn depends on the definition of written directive. However, if a written directive does not exist, that is, § 35.32 is not required for Agreement State licensees (i.e, category D), to specify (for example): the patient, route of administration, total dose, dose per fraction, treatment site, etc. the definition of misadministration would be rendered meaningless. While a definition for written directive would exist in § 35.2, only § 35.32 requires that a written directive be completed. Unless § 35.32 is required for Agreement State licensees (i.e., category A or C), they could not be required to have written directives, an effective misadministration definition, and or meaningful misadministration reports. (If any doubt exists about whether this is possible among the Agreement States consider Wyoming, a non-Agreement State, with no radiation protection program for non-agreement material and California whose radiation control program director has stated in public at the All Agreement States Meeting and the Conference of Radiation Control Program Directors Meeting that California will not adopt § 35.32.)

This means that the compatibility category for § 35.32 and selected definitions in § 35.2 should be at least C.

3. Consider whether § 35.32 should be classified as compatibility category C because if it is category D Agreements States would be free to not adopt it, a gap would be produced, and the orderly pattern in the regulation of agreement material on a national basis would be jeopardized.

Recall that § 35.32 protects patients from therapy overdoses by requiring that the administered dose be "close to" the prescribed dose, in accordance with the "closeness" criteria provided in the definitions of misadministration (e.g., within 20%).

If the compatibility category for § 35.32 were D (i.e., not required for Agreement State licensees) and all Agreement States in response to local pressures and priorities decided not to adopt § 35.32, consider whether there would be a gap between NRC and Agreement State programs to ensure adequate radiation protection for therapy patients or whether this would jeopardize an orderly pattern in the regulation of agreement material on a national basis. Clearly the gap would be about as large as it could get, since this would be a case of the haves versus the have-nots regarding radiation protection, and there would be no orderly pattern in the regulation of agreement material.

Now let's change perspectives. Regarding the overall issue as well as concern for State autonomy and flexibility, the first recommendation is to request that Congress change the Atomic Energy Act so that the NRC would be responsible for setting the performance standards and regulatory requirements for all radiation therapy sources for medical use licensees. Also, the participating States would be responsible for implementing, licensing, and inspecting those standards and requirements for their facilities; the NRC would be responsible for implementing, licensing, and inspecting the federal facilities and non-participating State facilities; and the medical use licensees would be reimbursed for the services provided to their patients if they maintained compliance with the performance standards and regulatory requirements. This approach is modeled after the Mammography Quality Standards Act. The disadvantage is that it requires changing the AEA, which is an uncertain and possibly slow process. The advantages are: that a federal agency with a national perspective and the ability to do any required research would set the performance standards and regulatory requirements; a State could decide on its own whether to participate, could participate in setting the national standards and requirements, and would control the compliance of licensees in its state; the licensees nationwide would have a level playing field and a clear understanding of what is required and why; and adequate protection would be ensured for patients and members of the public.

The last recommendation, assuming the current scheme of things, is to tailor implementation of § 35.32 by focusing regulatory attention and resources on high risk therapy procedures (i.e., those with severe consequences, like morbidity and mortality) and using specific performance standards for licensees. This rule is already fairly focused on therapy procedures, but its scope could be refined to exclude dosages of I-131 below 1 millicurie and include changes in therapy procedures. Also, the dose limits in misadministration definition (6) could be raised from 5 rems (whole body) to an individual and 50 rems to any organ to higher levels, but below morbidity; and brachytherapy fractional treatments could be specifically included in the definition of misadministration. Performance standards would need to be established for each treatment modality. This is assuming that performance should ultimately be measured against a "standard of goodness." The currently required and reported licensee data on the frequency of

occurrence of each type of misadministration for each treatment modality (e.g., therapeutic radiopharmaceutical dosages, teletherapy total doses, teletherapy weekly doses, and brachytherapy doses) would be used as the numerator for the performance standard. The denominator in each case could be provided by the licensees because they have billing records for each therapy treatment. For each licensee with "poor" performance the Commission could request that the licensee provide the performance data for each treatment modality and type of misadministration (e.g., number of teletherapy weekly administered dose misadministrations divided by the total number of teletherapy weekly administered doses in the last 12 months, and over the life of the license) and the licensee's plan for preventing such poor performances. The Commission could decide what constitutes poor performance and too much patient risk (i.e., expected loss or frequency of occurrence times expected consequences) either on a case-by-case basis or, through experience, establish specific performance standards such that the performance measurement must be less than 1 in 1000, 1 in 10,000, or 1 in 100,000. This would allow the inspections to focus on questions, such as, is the licensee maintaining the program, is the licensee detecting the misadministrations and recordable events, and does the licensee's performance measure up to the Commission's standards for each treatment modality? If the licensee's performance does measure up, then the licensee should be commended.

ATTACHMENT 8

DCD(SP(2)

RLSL
PHL
SLD
CNM

ARIZONA RADIATION REGULATORY AGENCY

Fife Symington
Governor

Aubrey V. Godwin
Director

4814 South 40th Street Phoenix, Arizona 85040-2940 (602) 255-4845
Fax (602) 437-0705

January 3, 1997

Paul H. Lohaus, Deputy Director
Office of State Programs
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lohaus,

In reviewing the discussions related to 10CFR35.32, it appears that some additional information should be provided to the Commission. I request that this accompany the attachmes. of Mr. John Telford to the Commission. These are my personal comments and do not represent the Working Group

In reviewing 35.32, I evaluated the applicability of the various criteria of each category. The resulting interpretation follows.

1. With regard to category A, I do not believe that the numerical values referenced in this section qualify as a primary standard for radiation protection as used in the Policy Statement.

2. With regard to category B, the interstate affects of not having 35.32 are not sufficient to justify a category B listing.

3. With regard to category C, there will be no gap, duplication or prohibition of a necessary practice if a state does not adopt this requirement.

4. The remaining category is D. The issue becomes "is there enough health and safety problems generated to require a H&S in the comments section." Based on the following information, I do not believe that a H&S note is needed.

   A. The requirement of paragraph (a) that a licensee maintain a quality management program to provide "high confidence" .. The term "high confidence is not defined and is somewhat vague. For example, does this mean that the program must be 90%, 95%, or 99% correct. Since it is vague, it doesn't appear to be a health and safety issue. In my opinion, a health and safety issue must have specific limits or guidance and thus does not. The associated Regulatory Guides do not sufficiently clarify the situation. The guides clearly state that they are not the requirements, only the regulations are the requirements. Further, the section appears to address standards of medical practice rather than pure health and safety. It should be noted that exposures to the

SP-97-1

9701060080 2pp.

public as a result of releasing a patient containing excessive radioactive material would appear to be reportable if a member of the public (not the patient) is exposed in excess of 0.1 rem TEDE. Similarly paragraph (a)(5), again, is not definite as to what the appropriate actions shall be and the licensee may believe that the appropriate action was taken only to be second guessed by the inspector. Again, the lack of specificity indicates that this is not a candidate for designation as H&S.

B. The remaining portions of 35.32 are very prescriptive and detail requirements which may be in conflict with record keeping requirements of groups like State Medical Licensing Boards and State Pharmacy Boards.

C. The NRC staff of the Working group may have felt some influence to support the H&S designation by the comments in the Statements of Consideration for 35.32 which indicates that the than Commission believed that the QM requirements were of safety significance. I do not feel so influenced, and therefore, have offered these comments.

D. In reviewing 35.32 one is drawn to the conclusion that the intent of the rule is to address the quality of medical practice rather than a health and safety issue. The regulation of the quality of medical practice as well as most professions is at the state level. The possible exception is the Mammography Quality Standards Act, but even that program has performance based rules rather than detailed prescriptive requirements.

Thank you for this opportunity to offer these comments.

Sincerely,

Aubrey V. Godwin,
Director