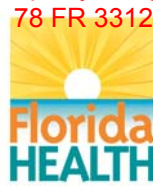


Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

September 16, 2013

Secretary, U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-001
Sent only via e-mail to Rulemaking.Comments@nrc.gov

RE: Docket ID NRC-2013-0081 Response to NRC Request for Comments Regarding Policy Statements "Adequacy and Compatibility of Agreement States" and "Statements of Principles and Policy for the Agreement State Program"

Dear Mr. Secretary:

Thank you for the opportunity to comment on these very important policy statements. We are aware that these policy statements will be guiding documents for changes to several important Management Directives regarding how NRC audits Agreement States. Enclosed in Attachment A and B respectively are Florida's responses to the policy statements as referenced above.

These comments are made having been involved in NRC audits since 1985 and also participating as a state representative on numerous NRC IMPEP audit teams. These comments are also made in a regulatory climate that all rules are carefully considered, before proceeding to determine if necessary, their impact, and to reduce redundancies. NRC is also going through a similar process "Cumulative Effects of Regulations (CER)" as directed by the Commission (See ML 12223A162 and ML13135A267). This process requires NRC to revise office rulemaking procedures to enhance the process, consider application risks and insights to prioritize regulatory actions, to consider other regulatory instruments and to quantify the cumulative impacts of regulations.

Please contact me if you have any questions or need further clarification. My phone number is (850) 245-4043 or you may reach me by e-mail at Mike_Stephens@doh.state.fl.us.

Sincerely,

Michael N. Stephens
Environmental Program Health Consultant
Bureau of Radiation Control
www.doh.state.fl.us/environment/radiation

MNS

cc: Cynthia Becker, Bureau Chief

Enclosures:

- A Comments on Proposed Revision to Policy Statement on Adequacy and Compatibility of Agreement State Programs Listed in FSME-13-055
- B Comments on Proposed Revision to Principles and Policy for the Agreement State Program

Enclosure A
Comments on Proposed Revision to Policy Statement on Adequacy and Compatibility of
Agreement State Programs Listed in FSME-13-055

PURPOSE Section:

We agree with the addition of the clarification that “public health and safety” includes physical protection of agreement material. Listing this statement early in the document limits the redundancy of repeating it in each section. We also agree with the use of the term “physical protection” instead of “security”.

We do not understand why NRC sees the need to add the phrase, “Nor does this Policy Statement diminish or constrain the NRC’s authority under the AEA.” It is obvious that the requirements specified in the AEA are the Law and cannot be diminished or constrained by any statement of policy. This statement adds nothing to the policy, is redundant, and should be removed.

BACKGROUND Section:

The language used to explain the requirements of AEA 274 follow the text of 274 closely except in the case of 274b, which uses the original word “discontinuing” instead to the proposed word “relinquishing”. We do not understand why the explanation of 274b differs from the actual AEA.

We agree with and support the addition of the phrase, “In identifying those program elements for adequate and compatible programs, or and changes thereto, the NRC staff will seek the advise of the Agreement States. The Commission will consider such advice in its final decision.”

Since this action has to be taken, it does not belong in the BACKGROUND section. We recommend that this phrase be added at the end of the DISCUSSION section.

DISCUSSION Section:

As mentioned above paragraph, move the phrase from the end of the BACKGROUND section to the end of the DISCUSSION section.

1. ADEQUACY:

1. ADEQUACY: A Legislation and Legal Authority

The last paragraph makes a subtle but very significant change. We recommend that the original text in the 1997 Policy Statement be used.

The original text states:

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.

The proposed text states:

For those items that have significant health and safety implications, the NRC shall identify legally binding requirements that should be adopted by Agreement States. The NRC expects that there will be a limited number of such requirements.

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Comments on Proposed Revision to Policy Statement on Adequacy and Compatibility of
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- The proposed text moves the attention from having these legally binding requirements because of each one's particular health and safety significance;
- The proposed text also constrains NRC to have a limited number of these while the original text limits the number based on the particular significant health and safety events.
- The proposed text actually moves the focus from a particular health and safety statement and makes NRC consider limiting the numbers because they think they have already issued too many requirements. This is a significant change.

The original 1997 text provides NRC more flexibility in addressing particular health and safety events without limiting the number based on the number of "events" instead of requirements.

Again, we recognize that this language shift is subtle but it is very significant and we recommend that the original text in the 1997 Policy Statement be used.

1.ADEQUACY: B – E No comment

1. COMPATIBILITY

In the first paragraph, the sentence "Those program elements are generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications" is vague and capricious because the word "generally" may mean anything.

We recommend that the word "generally" be changed to "should be" and the proposed text read "Those program elements should be limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications."

Category A and B

No comment.

The proposed changes clarify the meaning. My experience with multiple IMPEP audits with different Agreement State regulations and writing regulations in Florida is that these categories do not need revisions.

Category C

We recommend that in the last sentence delete the phrase "however, they should not be so restrictive as to prohibit a licensed activity." We recommend that this sentence be changed to "Agreement State program elements may be more restrictive than Commission program elements."

If it is a requirement that an Agreement State wants to prohibit a licensed activity because of health and safety or physical protection reasons then they should be able to do so under Category C. Putting this disclaimer in Category C blurs the line between Category B and Category C. If NRC does not want a regulated activity prohibited by an Agreement State then it must meet Compatibility B criteria. Agreement States must have the flexibility to tailor their regulations based on their business processes and the states health and safety considerations under category C.

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Should this requirement be kept, then we would not meet the Category C designation for the generally licensed devices under rule 31.5. We prohibit possessing all generally licensed devices (except tritium exit signs) unless the device is registered with the state and a per device fee is paid. We strongly feel that all generally licensed devices must be tracked and accounted for instead of a small subset of isotopes and activities listed in NRC's 10 CFR 31.5. We have registered all devices since early 1980 and we use the per device fee to inspect these facilities. Failure to register or pay the fee and we will prohibit this general licensed activity. In addition, some states require specific licensure for the devices listed in 31.5 due to their concerns for health, safety and security of the devices. Allowing this provision would automatically put them as not compatible because they take a more aggressive health and safety posture than NRC.

Some Agreement States also issue regulations to require certain elements that are only an NRC policy requirement listed in NRC's NUREG 1556 guidance documents. For example, Florida has regulations NRC does not have regarding the use of fixed and portable devices and the possession and use of unsealed radioactive materials not listed in other regulations. (E.g. laboratories, R&D facilities, nuclear pharmacies, manufacturing and distribution facilities, consulting services, etc.) NRC licensing requirements are described in the NUREG 1556 guidance documents. Should an applicant not meet these requirements as described in our regulations, then the licensed activity is prohibited. We would automatically not be compatible with NRC because we have regulations that prohibit a licensed activity that NRC does not even regulate.

Do not blur the distinction between Category B and C. Agreements States must have the flexibility to be completely more restrictive than NRC under category C even if that includes prohibiting a licensed activity.

Therefore we recommend that the statement "however, they should not be so restrictive as to prohibit a licensed activity" be removed.

Category D and E. No comment.

SUMMARY AND CONCLUSIONS:

We recommend that the last paragraph be returned to its original text as in the 1997 Policy Statement.

As discussed in the ADEQUACY Section above, the change in the proposed text is subtle but produces a significant change. Since this is a summary and conclusion section of the material listed above, the reasons under ADEQUACY are the same as above.

The proposed text moves the attention from having these legally binding requirements because of each one's particular health and safety significance. The proposed text also constrains NRC to have a limited number of these while the original text limits the number based on the particular significant health and safety events. The proposed text actually moves the focus from a particular health and safety statement and makes NRC consider limiting the numbers because they think they have already issued too many requirements

We recommend using the original language which states:

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Agreement State Programs Listed in FSME-13-055

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

TOPICS FOR ADDITIONAL COMMENTS

Comment 1.a)

We recommend that the phrase “significant and direct” be used instead of “particular”.

Comment 1.b) and 1.c)

We recommend that examples should be kept in the policy statement. NRC should consider adding a disclaimer that these examples are not all inclusive to avoid misinterpretations.

Comment 1.d)

As indicated previously, we recommend that the original text of the 1997 policy should be retained. If it is expanded or revised it should be limited to saying “significant and direct” with examples and a disclaimer discussed in 1.a) and b) above.

Comment 1.e)

The NRC should absolutely not consider economic factors in making a compatibility B designation, or any compatibility designation. This is not part of the AEA agreement and States must have the flexibility to fund their programs according to their needs.

Also, Florida, (as with any state) must go through their unique cost/impact economic analysis as part of the rule making process. Florida’s rulemaking economic consideration is required by statute and if a certain cost in a five year period is exceeded, the rule must be ratified by the legislature. If economic factors were part of the compatibility determination and it conflicted with Florida Statutes, we would not be compatible with NRC.

Comment 1.f)

We strongly recommend retaining the original 1997 text “The Commission will limit this category to a small number of program elements (e.g., transportation regulations and sealed source and device registration certificates) that have significant transboundary implications.”

Changing this wording deemphasizes that the agreement states should be given the flexibility when addressing the majority of program elements necessary for a compatible program and is contradictory to the closing paragraph above.

NRC should not think that by keeping the original text in any way limits their authority to make necessary rules to protect public health and safety. This is clearly authorized by the AEA and any “statement of policy” cannot be considered to change the Commissions authority.

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Comment 2.

We recommend that the original 1997 text be retained.

“The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. At the same time, requirements in these compatibility categories will allow the Commission to ensure that an orderly pattern for the regulation of agreement materials exists nationwide. The Commission believes that this approach achieves a proper balance between the need for Agreement State flexibility and the need for a coordinated and compatible regulation of agreement material across the country.”

The changes proposed will tend to make Agreement States become “NRC Clones” in how they run their programs. Due to different organizational structures, funding sources, business processes, rulemaking processes, and many other factors, the Agreement States must have the flexibility to run their programs dictated by their state governments and not NRC.

Comment 3.

We agree with the concept of alternative methodologies to compatibility than relying on a 3-year time frame to adopt rules. Perhaps some thought can be put into changing the Management Directive to have “important” rules vs. minor rules. Currently they are weighted the same. Currently the Management Directive allows alternative approaches to rules such as license conditions and orders. This would also be consistent with NRC “Cumulative Effects of Regulations (CER)” (See ML 12223A162 and ML13135A267) where rules are prioritized.

We recommend that the text on the Policy Statement on this issue remain the same as the 1997 text and appropriate changes be addressed in the Management Directives.

Comment 4. (1) and (2)

The use of metrics system was tried by NRC prior to the IMPEP process where Agreement States has over 30 metrics to satisfy to be deemed Adequate and Compatible. These audits were also conducted every 18 months and later changed to two years. This process did not really reflect whether states were adequate and compatible. For example, one of the metrics was that a State should have 1.5 FTE per 100 Specific Licenses. This was a meaningless number because of states business processes and the fact that they regulated other radiation hazards (x-rays, linear accelerators and NARM). These audits required much more state resources to conduct and usually were performed by one or two NRC people. Also, the metrics used were weighed in favor of large Agreement States to comply.

The current IMPEP process looks for performance, not numbers and essentially is a “holistic” determination of an Agreement State's Adequacy and Compatibility. NRC also should not try to combine adequacy and compatibility into a single finding because they are two completely different items.

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Agreement State Programs Listed in FSME-13-055

NRC should also take great care in adding metrics to the current IMPEP process. For example, the one metric currently used is the Status of Inspections. If a state has over 25% of new and priority 1, 2, 3 inspections overdue, they are unsatisfactory. For a small state with few of these licenses this is a small number (13 of 50) but a large state may miss the same number but be okay (20 of 200). Which is worse? The fact that you have over 20 past due inspections vs. 13 or that you are 10% in one case but 25% in the other.

Any use of metrics in the IMPEP process needs to be carefully considered and be part of the Management Directives not the policy statement.

SUMMARY:

We appreciate NRC's decision to review a process approved back in 1997. Any process needs to be looked at periodically for improvements. We believe that the current 1997 policy statement is adequate and is serving the needs of both NRC and the Agreement States. Yes, there may need to be some tweaking but this should be done in the Management Directives that implement the policy and not the policy itself.

As a reminder how well IMPEP works is the fact that NRC received special recognition.

In 2004, NRC's IMPEP program was selected among the top 50 programs for the "Innovations in American Government Awards" sponsored by the Ash Institute for Democratic Governance and Innovation at Harvard University's John F. Kennedy School of Government and administered in partnership with the Council for Excellence in Government. (See [ML050980157](#)) The top 50 programs were chosen from a pool of nearly 1000 applicants and represent the best and brightest in government (See <http://www.govtech.com/e-government/Semifinalists-Announced-for-Innovations-in-American.html>)

Enclosure B
Comments on Proposed Revision to Principles and Policy for the Agreement State Program
Listed in FSME-13-055

E. Performance Evaluation

The first paragraph of the proposed text states NRC will “ensure they will continue to be adequate and compatible after an agreement becomes effective.”

Recommend that the word “ensure” is deleted. NRC may make a finding whether a state is adequate and compatible but they cannot “ensure” it.

NRC Actions as a Result of These Findings.

2. Probation

The last sentence does not provide the Commission the opportunity to place a State currently on probation to heightened oversight at the end of the probationary period. The only options are to continue probation, suspension or termination.

A situation may arise where the State has addressed all of the “significant” deficiencies and would warrant being placed on heightened oversight instead of continuing the probationary period for minor deficiencies.

Recommend that the text be changed to provide the Commission the option of going to heightened oversight from probation.

RulemakingComments Resource

From: Mike_Stephens@doh.state.fl.us
Sent: Monday, September 16, 2013 4:36 PM
To: RulemakingComments Resource
Cc: Cindy_Becker@doh.state.fl.us; Mike_Stephens@doh.state.fl.us
Subject: Docket ID NRC-2013-0081
Attachments: FLComments-ID NRC-2013-0081.pdf

Dear Mr. Secretary:

Please find attached our comments on Docket ID NRC-2013-0081.

Please contact me if you did not receive the attachment or if you have trouble opening it.

Sincerely,

Mike Stephens

Michael N. Stephens, M.S.

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How are we doing? Please take our survey: <http://www.doh.state.fl.us/environment/radiation/survey.htm>

Our mission is to protect & improve the health of all people in Florida through integrated state, county, & community efforts.

Our Vision is to be the Healthiest State in the Nation

Our Values (I CARE):

- I**nnovation: We search for creative solutions and manage resources wisely.
- C**ollaboration: We use teamwork to achieve common goals and solve problems.
- A**ccountability: We perform with integrity and respect.
- R**esponsiveness: We achieve our mission by serving our customer and engaging our partners.
- E**xcellence: We promote quality outcomes through learning and continuous performance improvement.

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.