Organization of Agreement States

October 21, 1996

U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sirs:

As you know, there are currently 29 states that have entered agreements with the NRC under Section 274 of the Atomic Energy Act of 1954. The agreement state program is an excellent example of the ability of states to conduct regulatory programs in an effective and efficient manner. The Organization of Agreement States (OAS) provides a vehicle for Agreement States to interact on common issues that affect individual states or all 29 Agreement States.

The OAS has received comments from individual Agreement States on the Direction Setting Issue Papers issued as part of the NRC's Strategic Assessment of Regulatory Activities. These comments have been summarized for each of the Direction Setting Issue Papers and are attached for consideration in this matter. Many of the individual Agreement States will provide state specific comments as well.

If you have any questions, please contact me.

Sincerely,

Richard A. Ratliff for

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Organization of Agreement States

Comments on

U.S. NRC Strategic Assessment and Rebaselining Initiative

Direction Setting Issue Paper #7
"Materials/Medical Oversight

The Organization of Agreement States (OAS) supports the concept of a consistent and unified national program for the regulation of all sources of ionizing radiation. It makes little sense to continue to divide radiation programs according to archaic historical distinctions. However NRC's Strategic Assessment and Rebaselining Initiative Stakeholder Involvement Process Paper falls short in addressing all radiation safety issues and doesn't provide a complete perspective on this issue. Little mention is made that the majority of radiation exposure is from non-AEA sources and thus gives the impression that only minor changes to NRC's program are needed. Further, it appears to provide questionable information to support its own conclusions. For example, the statement that it would take "several hundred" FTE's to regulate discrete NARM is highly doubtful. NRC should work closely with the Agreement States on this important issue as they have greater regulatory responsibility and collectively regulate about 70% of AEA material and almost 100% of all sources of human radiation exposure.

OAS supports efforts to identify regulations that are unnecessarily burdensome, duplicative or too prescriptive. This is especially needed for Part 35 regulations. The option of using a risk-based approach is supported by most states however such criteria must be uniformly applied to both existing and proposed regulations. Identification and classification of "low-risk" activities must be done in conjunction with Agreement States. The NRC must not abandon regulatory control over "low-risk" activities solely to reduce its regulatory burden. Such an action could result in additional problems faced by all radiation control programs such as the problem of poorly controlled generally licensed devices.

Since Agreement States have broader regulatory authority and experience with regulating all sources of radiation, it is strongly suggested that the NRC consult with the Agreement States prior to finalizing its position on this issue. The following are individual comments on DSI -7.

Colorado

1. A valid option that should be considered is to increase regulatory responsibility with the addition of NARM. The proposed Option 1 (assume control over NARM and x-ray) is too broad a mission change, while increasing with just NARM requires no new skills of staff, eliminates duel regulation at hospitals, moves toward fulfilling a request the states have often made - that NRC oversee NARM.

2. In response to the question of NRC striving to encourage more states to become Agreement States, see comments under DSI 4.

3. Page 11 states an item to be considered is the interpretation the Commission has adopted that medical patients are included in the "public". This DSI neither discusses the issue further nor asks for comments from the public. Our opinion is that patients be protected through the regulatory framework. State representatives at the Agreement State meeting in Vancouver, Washington also reached this conclusion. This opinion should be continued unless there is strong arguments from many groups against it.

4. Page 15 states it would take several hundred FTE's to promulgate discrete NARM regulations appears excessive. Since NARM is similar to AEA materials, incorporation should be more procedure than divergence into new frontiers.

Illinois

The Direction Setting Issue (DSI)--"What should be the future role and scope of the NRC's Nuclear Materials Program, and in particular, NRC's regulation of the medical use of nuclear material?"

Although this DSI purports to address all material oversight, the vast majority of the paper focuses only on the medical area. The Department is in support of the NRC's initiatives to streamline the licensing process, eliminate duplicative or contradictory regulations, and update regulatory guidance for all categories of licensees, not just medical licensees. However, we would caution the NRC not to abandon the regulation of radioactive material altogether. The use of radioactive material in this country is safe for workers because there are established requirements for users of radioactive materials. The public is protected because of the regulatory community's diligence in ensuring that individuals using radioactive material do so safely. In some cases, it is necessary to modify the regulations to be less prescriptive, but it is not necessary to relinquish all controls over the safe use of radioactive material. In fact, it is appropriate for the NRC to consider expanding its regulatory

authority to establish uniform safety standards for all forms of ionizing radiation.

Specific Comments

Option 1

As indicated on Page 15 of DSI 7, Agreement States are in support of establishing one federal agency to work with the states to establish basic standards for all uses of radioactive material. We recognize that this is a major departure from NRC's current approach, however, we believe it makes sense to treat all ionizing radiation equally. A rem to an individual is still a rem, whether it comes from Co-60, Ra-226 or an accelerator.

Although this report states that it would be difficult to support legislation to address all sources of ionizing radiation "in the absence of a compelling safety problem," we find that argument to be short-sighted. As indicated throughout this DSI (and DSI 2 and DSI 4), many state regulatory agencies already have established programs to address all uses of ionizing radiation in their respective states. States did not wait for an incident to develop a program, but have been pro-active in ensuring the safety of workers and the public. In fact, it may be that the states are in a better position to oversee certain DOE operations because the state programs are more encompassing.

The report's estimate of several hundred FTE's to regulate discrete NARM possessed by persons in non-Agreement States and by federal agencies is outrageous and without any foundation. The NRC need only ask the Agreement States about the marginal impact of regulating discrete NARM sources in their states. An elementary assessment of the "several hundred" statement would mean that the effort to be applied to discrete NARM is vastly larger than the resources now devoted to agreement materials. That is incredulous. The NRC does not need to go down this path alone. States with experience in regulating NARM are willing to share their expertise and experience.

Option 2

As stated above, we support the NRC's efforts to identify regulations that are obsolete, unnecessarily burdensome, duplicative or too prescriptive and the NRC's work to modify or delete these regulations. We also support the NRC's efforts to streamline the licensing process. The modifications made to-date through the BPR should benefit up to one third of the NRC's licensees (measuring system licensees). We agree that this option should continue to be pursued.

Option 3

We strongly urge the Commission to reconsider its support of Option 3. A joint NRC-Agreement State Working Group on devices recently reported that problems associated with the NRC's general license program included inadequate regulatory oversight, inadequate control and accountability of devices, and improper disposal of devices. The working group developed strawman solutions and recommendations aimed at regaining control of the use of both generally-licensed and specifically-licensed devices. These recommendations included requirements for users, distributors and regulatory agencies. Option 3 of this DSI, however, recommends minimal regulatory oversight, minimal licensing requirements, and the possible elimination of inspections.

As written, it appears that Option 3 is advocating regulation of only "high-risk" activities. We agree that some streamlining commensurate with risk is warranted, however, we are firmly opposed to abandoning requirements for all "low-risk" activities. The regulations supposedly are written to minimize risk to workers and the public. Proper training and use of radioactive material will result in lowering any risks associated with using radioactive material. If you remove the regulations designed to limit the risk, you can no longer ensure that a "low-risk" activity will remain such.

Option 4

The NRC should not discontinue the regulation of all medical activities, just as it should not discontinue the regulation of all other uses of radioactive materials. It is vital that the NRC recognize the professional views of the Agreement States, physicians, physicists, pharmacists, hospitals and professional organizations regarding the unnecessarily burdensome, detailed and prescriptive requirements of Part 35, and make modifications. To assist in determining the proper course of action, the NRC, FDA and representatives from applicable boards of medicine and pharmacy should jointly develop a paper describing the jurisdictional boundaries of each entity relative to regulating the use of radioactive material and the practice of medicine. Such a document would be a great reference point to begin recalibration of the applicability of existing regulations.

We would like to point out that there are numerous references to a "consensus" of Agreement States on the IOM recommendations at the technical workshop held March 5-6, 1996 (see pp.21, 25 and pp. 17, 24, 25, 26, and 29 of the Attachment). The NRC has been cautioned that the March workshop was primarily a meeting of technical state staff and not policy makers or program directors. This has been a problem with other NRC sponsored meetings. While we do not think Agreement State

policy makers would substantially disagree with the workshop attendees, a better reflection of ALL state views is contained in the position passed by the CRCPD on May 8, 1996.

Based upon discussion topics from DSI 2, the Department of Veterans Affairs may need to reconsider its position that legislative initiatives should ensure that federal facilities are not subject to state and local regulations (Page 21, Paragraph 2). Under some circumstances, it may be appropriate for states to regulate federal facilities, and we oppose self regulation of medical uses by federal facilities.

Option 5

As indicated in our comments on Option 3, the NRC must not simply discontinue its oversight of the use of radioactive material. It is unreasonable to assume that individual states and federal agencies would self-regulate to the same degree. This could cause problems for facilities doing business across state borders. Deregulation of radioactive material sends the message that the material is inherently safe, a sentiment that Congress is unlikely to agree with.

Section V. Commission's Preliminary Views

We agree with the Commission's preliminary views regarding Option 2, and caution the Commission to consider possible problems encountered with deregulation of "low-risk" uses of radioactive material. Time and resources would be better invested and a greater number of citizens would benefit if the NRC would spend more time visiting and inspecting facilities, rather than spending those resources imposing civil penalties, which seems to have become a routine practice.

We do not believe there should be encouragement for non-Agreement States to develop programs to regulate only medical use. This effort to segregate medical uses from a comprehensive radiation safety regulatory program raises questions about unequal treatment of medical licensees as compared to other licensees, such as measuring systems licensees. For additional comments on this issue, please refer to the CRCPD position dated May 8, 1996, on the NAS-IOM study.

Other Comments

Page 10, Paragraph 4

Although this section has no specific guidance, any effort to ameliorate the full cost recovery problem should not be linked to Agreement States, present or future.

NRC must look to other mechanisms to solve that problem.

New York State Department Of Labor

In keeping with our comments on Direction Setting Issue 4 (NRC's Relationship with Agreement States), we strongly recommend adoption of Option 5, turning over all regulatory authority for Atomic Energy Act (AEA) materials to the states, which could be preceded by Option 3 during a transition period.

Option 5 is in accordance with the recommendations of the NRC National Performance Review Steering Committee, and in accordance with the National Academy of Sciences Institute of Medicine recommendations for NRC's medical regulation program.

We would also emphasize again (as in our comments on DSI 4), the economics of the situation. Options 5 is the only reasonable hope that NRC licensees have to contain or reduce their fees, since the other options would make only trivial differences. Eliminating 50% of NRC's remaining licensees, for example, would only eliminate 50 staff positions according to this paper. However, there is no estimate of the effect that this would have on fees for the remaining 50% -- perhaps they would increase due to the smaller licensee base.

We also note that this paper expresses a concern that turning over all regulatory authority for AEA materials to the states could be considered an "Unfunded Mandate," and viewed as subject to the Unfunded Mandate legislation. this is presented as an argument against Option 5. Strangely enough, concern over unfunded mandates didn't enter into the discussion in DSI 4 of the Commission's possible recommendation that ABRA-90 be modified so the NRC could charge Agreement States to recover its "oversight" costs

So on the one had, it is argued that states should not be burdened by the unfunded mandate of the NRC's turning its materials program over to them, while on the other hand, Agreement Stated, which have voluntarily accepted an unfunded mandate, will only be considered co-regulators and equals if they paid part of the expenses of the federal agency whose work they have taken over!

Two strong themes running throughout many of the NRC "Direction Setting Issue" papers are its shrinking licensee base and money. The themes are inexorably linked since NRC is required to recover all operating costs from licensees. As the number of licensees declines, fees rise and this accelerates the decline by causing licensees to give up their licenses or even relocate to Agreement States. This should be seen as a natural process driven by Section 274 of the Atomic Energy Act, which created the Agreement States program. The more successful the Agreement States program is (i.e., the more states that accept responsibility for "Agreement" materials and add them to their radiological health programs), the more marginal NRC's program becomes and the more difficult to support. Since states now regulate 70% of "Agreement" materials licensees, and will soon regulated 80%, it is

rapidly becoming impossible for NRC to support its program by fees imposed on such a small number of licensees.

There are ways in which NRC could reduce its operating costs, such as eliminating its costly and extensive practice of contracting out work that cold be done by its own technical staff, and reducing its research and rulemaking activities to those that are truly necessary to protect health and safety.

They could also save substantial amounts by adopting rules already developed by Agreement States (such as Industrial Radiography and Well Logging regulations) and adopting cost-effective practices already used by Agreement States to expedite licensing and inspection activities. Instead, NRC chose to discontinue the training it formerly offered to Agreement States, at a trivial savings of one-half million to one million dollars a year.

However, although such cost containment actions should certainly be undertaken as interim measures, they are not the solution. The solution is for NRC to recognize that what is happening is the desired outcome for the Agreement States program: the successful transfer of regulatory responsibility for Atomic Energy Act Section 274 materials from NRC to the states. Having achieved that goal, there should be no question that Section 274(a)(6) of the ACT must now be implemented. That provision states that "as the states improve their capabilities to regulated effectively such materials, addition legislation may be desirable." this legislation would properly be t amend the AEA to withdraw the federal preemption of AEA material, and restore them to the universerse of radiation sources already regulated by the states.

Unfortunately as in the DSI 4 paper, the Commission's preliminary views are basically to maintain the status quo with some decreased oversight over"low-rick" activities. Aside from the arguments we have already made against that amounts to a "no-action" option, this begs the question of who will pay for NRC's program if they insist on continuing it. there is no question our minds that the state will not.

In regard to NRC's proposal to decrease oversight of "low-risk" activities we have the following comments:

While the wording used in regard to defining "low-risk" is vague, we hope (and strongly recommend) that this will involve a risk-based reevaluation of all existing generally licensed and exempted radioactive materials in NRC regulations. The results of such a global reevaluation should be used to redefine and restructure these regulations, not just to move currently defined generally licensed and exempted material from one category to another.

we strongly recommend that this reevaluation include elimination of the general license given in 10 CRF Part 31, section 31.5, and reallocation of these devices to exempt or specific license status.

The proposal to transfer some current specific licenses to general licenses

appears to be an attempt at an ill-considered "quick fix" to reduce NRC's workload. We have submitted comments to NRC elsewhere (July 29, 1996 letter from Rita Aldrich to Carl Paperiello) on the problems inherent in "general" licenses which have resulted in accidents requiring millions of dollars to be spent in remediation. Our letter suggested more innovative ways of shifting resources to reduce burdens on both regulatory agencies and regulated parties.

Also, even though this proposal is planned to reduce 50% of NRC's current specific licensees to general license status, with a drastic reduction in oversight of these programs, only 50 NRC staff are expected to be eliminated as a result. We believe strongly that this proposal would result in a significantly increased risk to health, safety and property while producing negligible savings.

NRC should begin an immediate review of all of its regulations for AEA materials, with the objective of eliminating as many prescriptive requirements as possible. For example, although every licensee needs to implement a radiation protection program, the existing requirement to perform an annual audit of the program, and of the conduct of the radiation safety officer, is reasonable only for larger, more sophisticated programs. However, NRC's guidance for portable gauge licensees (one of the categories it now apparently wants to relegate to general license status) contains a four and a half page form to be used for such audits. this combination of a needless regulatory requirement, made even more onerous through "guidance" is not unusual. therefore, instead of seeking quick and easy fixes that may degrade the current level of safety, NRC should perform a thoughtful review of it regulation -- Part 35 in particular -- and its guidance documents for the expressed purpose of reducing regulatory burdens on itself and its licensees.

This regulatory reevaluation should be conducted concurrently with the implementation of Option 2 under DSI 4, since simplifying regulations, and making them performance-based and easier to implement, should in itself attract states to Agreement State status. the reevaluation should of course be conducted in close consultation with the Agreement States as NRC also works on implementation of Option 5.

Tennessee

Our review indicates that we favor a combination of Option 2 (Continue the Ongoing Program with Improvements) and Option 3 (Decrease Oversight of Low-Risk Activities with Continued Emphasis on High-Risk Activities). This is consistent with the change in regulatory oversight as new methodologies with low-risk have become more widely used over the history of medical regulation. We believe that the U.S. Nuclear Regulatory Commission should modify and enhance its program to regulate all radioactive materials, and, although we would reserve the right to comment further, we believe that the U.S. Nuclear Regulatory Commission should seriously consider regulating all radiation sources.

Tenesee's general assessment of the NRC's Strategic Assessment of Regulatory Activities is that the effort appears to be constrained so that ony select options are presented. In many cases, those options are analyzed or presented in a manner that does not allow a fair, unbiased assessment of one option versus other options. One particular example is the statement under DSI 7, IV. OPTIONS, Option 1, Impacts, which notes: *"Such wide-sweeping legislation may be difficult to support in the absence of a compelling safety problem."*

This statement is made to denigrate the safety problems that exist in the non-AEA radiation source arena (machine source, and NORM). This is very interesting in light of the daea that demonstrates that most exposure to ionizing radiation occurs in the radiation machine arena and that 50% or more of that is unnecessary. Similarly, the states find numerous situations involving NORM problems that expose the public to unnecessary radiation exposure well beyond the levels at which Atomic Energy Act (AEA) materials are regulated.

Thus the referenced statement would actually be more appropriately applied to the questioning need for continuing the current AEA legislation in light of the safety problems that are not addressed by the AEA. Why do we regulate AEA materials to the point of decreasing return, while ignoring the larger safety issues in machine produced radiation and NORM?

It was Tennesee's impression that this effort by the NRC was to start from zero to assess what it should be doing. The information presented actually appears to be developed to justify the continuation of the NRC activities as currently constituted. It is clearly not an unbiased full assessment of what radiation protection at the federal level should be. It is clearly not even an unbiased full assessment of what radioactive material radiation protection at the federal level should be.

In several DSI's the concept of state involvement is toyed with, but full assessment is never significantly considered in the specific options. For example, in each instance in which an option considers the NRC take on non-AEA sources great pains are made to elaborate on the necessary resources that this would require when all that may be required is recognitin of the resources that are in existence in the states. NRC need only become the senior partner in the operation, assuring consistency and compatibility among the programs.

Tennessee proposes <u>one</u> simple option for the regulatin of all radioactive material.

Texas

As stated in the Texas response to the recommendations of the National; Academy of Science, we support the concept of one federal agency for all sources of radiation. This combined with a commitment of that agency to risk-based regulations and programs, would ensure greater consistency of regulation of those sources.

Options 2 and 3--to improve the regulation of radioactive material and decrease regulation of sources that do not present a significant risk--should be implemented immediately and would be the options of choice if legislation to achieve Option 1 is not feasible. For example, all gas

chromatography sources could probably be generally licensed. Medical regulation needs to be rethought, especially diagnostic nuclear medicine.

Option 4 could be disastrous, since it would create yet another orphan use that is regulated differently than any other use of radioactive material. Option 5 might eventually be desirable, but could create an unfunded mandate for states, if the programs were simply handed over to the states.

We agree with the Commission's proposed choices. However, considerable consultation with the Agreement States must be utilized. Significant risk exists that either (1) further fragmentation of radiation safety regulation will occur; or (2) the NRC will continue to mandate regulatory requirements that have no health and safety basis. The important conclusion one should draw from the IOM report is not that medical radiation should be de-regulated, but that NRC implementation of prescriptive regulations was inappropriate and heavy-handed.

It was not clear how the NRC envisions the "related issues" to be purely a Commission issue as long as NRC controls Agreement State compatibility and adequacy determinations. In addition, it would seem strange not to consider input from licensees on these issues. This comment pertains to other DSIs.

It was noted in the issue paper on page 14 that the definition of discrete NARM included radium sources and wastes from cyclotrons, but left out important NARM sources in the medical arena, those being radiopharmaceuticals used for positron emission tomopgraphy.

5. The Commission's preliminary view may be appropriate. It is appropriate to apply a risk-informed performance based approach to the oversight of all regulated activities. However, the DSI does not provide enough discussion on the impact to the public, patients, licensees or public health and safety.

Washington

I support a combination of Options #1 and #3: ALL uses of radiation regardless of source (Option #1) should be regulated according to their relative risk of harm to humans (Option #3). We should have a consistent, uniform, national program for the regulation of ionizing radiation which necessarily includes NORM, NARM and x-ray as well as by-product material. It makes little sense to continue dividing the issue to radiation safety according to archaic historical distinctions. Whether the issue is "misadministration", generic machine defects, computer programming errors, or radioactivity in the environment, the regulatory requirements should be based on the health risk and apply equally to any source of radiation: NORM, NARM, by-product material, or machine produced radiation.

There should be a decrease in the oversight of "low-risk" activities while refining and emphasizing control over "high-risk" activities. However, this does not mean that "low-risk" activities can be automatically dropped to the current, poorly regulated "general license"

status. The appropriate level of regulatory oversight should be determined in concert with the Agreement States and the CRCDP.

Option 2 is not supportable since it infers that the current degree of oversight requires "only a little" modification. The fractiousness among that "improvements to increase efficiency" will be satisfactory. "Revision of regulations to make them more risk-informed and performance-based rather than prescriptive" is much more appropriate but should be done in the context of Option 3 which takes a broader look at all regulated activities of NRC.

Options 4 and 5 are not supportable because they represent a particular abrogation of federal responsibility which would lead to increasing fragmentation and disparity among isolated state radiation control programs across the nation. This would not provide consistent, uniform radiation protection for citizens as they move from one jurisdiction to another.

DSI-21

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NRC STRATEGIC ASSESSMENT AND REBASELINING INITIATIVE

DIRECTION SETTING ISSUE COMMENT FORM

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AFFILIATION Organization of Agreement States

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COMMENT:

See Attached

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