



Organization of Agreement States

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Paul H. Lohaus
Office of State and Tribal Programs
Mailstop O3 C10
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Mr. Lohaus:

The Organization of Agreement States (OAS) wishes to comment on behalf of its membership on changes to Part 35 regarding training and education (T&E) requirements. In addition, we wish to comment on NRC's consideration of reducing the Agreement State implementation period for the T&E requirements to less than 3 years (possibly 1 year).

As noted in the addendum to this letter, the OAS executive board sent a query by the Rad Rap list server on 3 related questions and encouraged interested states to comment. We took this action to facilitate feedback to questions made by NRC during the December 2004 OAS/NRC teleconference. OAS's comments contained herein are based on consensus provided by our membership in response to the query. Please see a summary of comments in the attached addendum.

First, none of the states that responded have yet adopted the T&E changes. Before moving forward, they intend to wait on final changes to Part 35 to avoid going to rulemaking twice on the same material. The consensus of the states is that a buffer of three years is needed to ensure adequate time for rulemaking. The OAS agrees. Given the scope of past and pending changes to Part 35, and the typical time required for states to adopt rule material, the OAS requests that a full three years be allowed for Agreement States to promulgate the rule changes.

Second, no clear consensus could be drawn from the responses as to whether T&E requirements should remain as compatibility category B. However, some very good observations were made.

- Consistency is needed so states and NRC can accept another agency's rules of adequacy for authorized users. This is of particular concern in adjacent states of small geographic size where it is fairly common for a physician to be licensed in several states.
- With the easing of credentials, individual Agreement States are forced to adopt rules they may view as inadequate. Whereas the Commission views the national spectrum, the states view local spectrums. The states are concerned that by being required to accept diminished rules, they are forced to subject their citizens to the jeopardy of unqualified users.
- Some of the states cited a conflict of interest in that ACMUI would push for reduction in health and safety requirements when they in large part represent the medical community that NRC regulates. The Commission, in the interest of health and safety, should have held the line.
- Resolution is needed on the amount of didactic training needed to comply with the rule, either through a clearer statement in the rule (as in Subpart J of the old rules) or through clear guidance that can be agreed to by both NRC and the Agreement States.

Pursuant to the compatibility category B issue, the OAS endorses the consistency between agencies. However, by reducing credentialing requirements, the health and safety of the citizens of our states has been potentially impacted. The OAS requests that the Commission re-strengthen the T&E requirements

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to better safeguard the health and safety of Agreement State citizens. The OAS requests the Commission to again implement specific requirements on the amount of didactic training through a clearer statement in the rule (similar to the old Subpart J). The OAS requests the opportunity for Agreement States participation in developing the rule material that clarifies said didactic training requirements.

Thank you for the opportunity for the Agreement States and OAS to comment on this important issue.

Most Respectfully Yours,

(Signature copy sent by mail)

Stanley Fitch, Chair
Organization of Agreement States

cc: Kenneth Weaver, Secretary, OAS

ADDENDUM

During the December 2004 OAS/NRC teleconference NRC mentioned its intentions to publish, in the following week's Federal Register, its proposed revisions to Part 35 T&E requirements. NRC requested comment from the Agreement States that were participating in the teleconference on the proposed revisions and the amount of time the States would need to implement the revisions under compatibility. NRC noted they were considering reducing the Agreement State implementation period to less than 3 years (possibly 1 year). Feedback was limited during the teleconference. To facilitate additional feedback, the OAS board sent a query by the Rad Rap list server on 3 related questions and encouraged interested states to comment.

These are the questions that were made in the Rad Rap query:

1. Has your State already implemented the reduced T&E requirements? If not, will your State be exercising the 3 years currently allowed for implementation?
2. Would your State experience difficulty implementing Part 35 revisions in a period of less than 3 years? If so, why? How much time is required in your State for implementation of new radiation safety rules?
3. The Commission has decided that the T&E requirements fall under compatibility category B. Do you agree with their decision? If not, what category should they fall under and why?

A number of states responded. Their responses are shown below. Some editorial license is exercised in that the names of the states and their respective agencies have been edited to be non-indicative of the commentator. The OAS believes that the concepts in the feedback should be stressed and not the individuals who actually provided them.

Following are replies received to question #1, "Has your State already implemented the reduced T&E requirements? If not, will your State be exercising the 3 years currently allowed for implementation?":

- A. Our state has not implemented the Part 35 T&E requirements yet. Hopefully it will not take the full three (3) years to implement this process, but that is dependent on public comment and legislative review.

On the category B requirement, I agree with the NRC and in doing so would expect consistency between states in being able to accept another states licensing of an individual as an authorized user. I don't have the time or money to read 50 different T&E requirements to ensure an individual meets our state's licensing laws.

- B. We would like to mirror above response. Until we see the actual proposed requirements, we cannot commit to anything shorter than the 3 years typically given.

- C. No, our state has not yet implemented the reduced T&E requirements and yes, we intend to take the full three years for implementation.

- D. We are in the final process of preparing a public hearing document to amend our radiation control regulations [estimated for actual hearing 1st quarter of calendar 2004] which includes all of our 10 CFR 35 equivalent with the exception of training. We are proposing to retain our 10 CFR 35, Subpart J equivalent requirements until we get a clearer picture of exactly what the final T&E requirements will look like. We see no benefit in adopting the current "new" T&E at this time and having to change it again in the near future.

We believe that these changes to the T&E requirements should be considered as a major amendment and not a "technical correction/clarification". Therefore, the full 3 year interval for adopting the revised T&E should start on the date they become effective, and not be retroactive to the date the remaining 10 CFR 35 amendments became effective.

- E. No. Once the final NRC rules are implemented, we will be incorporating the revised T&E into the full revision of our medical rules.
- F. No to the first question and yes to the second question.
- G. We have not implemented the NRC changes in the T&E requirements, since we were waiting on resolution of the Board certification issues in the rule, so that we would not have to amend our rules twice for compatibility. We will probably implement the rule within the next one to two years.
- H. Our state can report that we have not implemented them. Our time line for adopting the revised Part 35 has us with rules effective Nov 2004. We plan to add the T & E requirements along with our work to deal with the more sweeping changes in Part 35. (One rulemaking action instead of two.)

Following are replies received to question #2, "Would your State experience difficulty implementing Part 35 revisions in a period of less than 3 years? If so, why? How much time is required in your State for implementation of new radiation safety rules?"

- A. Typically, being short on staff and associated skills it takes close to the three year time frame. Without having seen the proposal, one (1) year is probably not realistic, even with minor change.
- B. Of course, we would adopt what the NRC promulgates as a final rule in the federal register because we are an Agreement State, but we will be examining the proposed rule carefully with implementation in mind.
- C. I'm not sure if we would "experience difficulty" in implementing in less than three years, but it is extremely difficult to get anything done around here, rule revision-wise.
- D. Our radiation control program has statutory authority to promulgate regulations under our Administrative Procedures Act. We do not need legislative approval/concurrence. This Act does allow for an "emergency" filing of regulations/amendments for a period of up to 120 days, which can be renewed once for an additional 90 days. However, if the "emergency" regulation/ amendments have not gone through the public hearing process and filed with the Secretary of State by the end of that 90 day extension, the amendments become null and void, and the regulation reverts to its original status. Therefore, while we do have a mechanism for a short turnaround, we would prefer to take the full allocated time for adopting the revised T&E. Our rationale for the delay is that we have been "burned" by NRC amendments in the past which we rushed to adopt, only to have NRC change their mind because of negative public response or other concerns (e.g., SSRCR Part W and Decommissioning Funding) and have to repeat the process a short time later.
- E. There is no justification for implementing changes to Part 35 sooner than required for other regulation changes. These changes are not "emergency changes" and should be allowed the same interval for inclusion as most other rule changes. Individual problems can be handled administratively. If these were "emergency rules" I could gain support for quick implementation by executive order. These changes should be given the same time frame for implementation as other rules. If states can implement the rules quickly, and want to, they will!
- F. Yes! Our agency's Regulations Committee is currently involved with other regulations packages that must be completed prior to working on the challenging review and adoption of Part 35. Time required for implementation is variable with complexity and level of legal review involved. Most regulatory

packages require a period of at least 15 months to produce a final draft because of essential operational activities and the ever present changing priorities. An itemization of regulations development follows:

- a. Review of NRC compatible regulations by Regulation Committee (periodically)
- b. Preparation of draft of supplement by Regulation Committee member (3 month average time depending on the size of the regulation and resources availability)
- c. Review of initial draft by Regulation Committee (3 month average time depending on the size of the regulation and resource availability)
- d. Submittal of draft regulation to Office of the Attorney General (OAG) and NRC (3 month average time at OAG depending on the size of the regulation and resource availability and 3-6 weeks at the NRC)
- e. Page formatting of regulations by Regulation Committee (2 month average time depending on the size of the regulation and resource availability)
- f. Submittal our state Division of Documents for approval of "Incorporation by Reference" format (2-3 weeks)
- g. Submittal to Children's Environmental Health and Protection Advisory Council. (2-weeks)
- h. Submittal to and signature by the Secretary of the Environment (15 days dependent upon whether clarifications are required by Administration's Senior Management)
- i. Submittal to Department of Business and Urban Development (DBED)(14 days)
- j. Submittal to Joint Committee on Administrative, Executive, and Legislative Review (AELR) (concurrent with DBED review)
- k. Publishing of Proposed Action in our state's register (wait to next publishing date following ALER approval)
- l. 30-day public comment period on Proposed Action.
- m. Address comments, if any. (2-months)
- n. After comments resolved, submittal of Final Action document for the Secretary of the Environment's signature (15-days)
- o. Publishing of Final Action in our state's register.
- p. Regulations become effective 10 days after publication.

G. As noted in our response above, we plan to start rulemaking as soon as the NRC amendments concerning T&E are finalized. This should take us about a year after that.

H. If we meet our time line, we will have adopted the T & E requirements prior to the end of the customary 3 year period.

Following are replies received to question #3, "The Commission has decided that the T&E requirements fall under compatibility category B. Do you agree with their decision? If not, what category should they fall under and why?"

- A. On the category B requirement, I agree with the NRC and in doing so would expect consistency between states in being able to accept another states licensing of an individual as an authorized user. I don't have the time or money to read 50 different T&E requirements to ensure an individual meets our state's licensing laws.
- B. We would like to again mirror the above comment in favor of the requirements being compatibility B. Our staff would not have the time to compare differences from other states either.
- C. We do NOT agree with the category B assessment, and find category "D" to be much more appropriate.
- D. Logically the T&E requirements have to be compatibility B. Otherwise, a physician might have to be "retrained" every time they moved to a different state. That may not be a big deal out West, but the

small geographic size of states in New England makes it fairly common for a physician to be licensed in several states. That having been said, I have to concur with Dave and the Part G Working Group that NRC "gave away the store" to the endocrinologists. The reduced training required makes absolutely no sense and basically opens the door for any other medical sub-specialty to lobby the Commission for special reduced training because their members "know what they are doing" and don't need additional training. I believe the Commission should realize that they now only license a fairly small percentage of the nuclear medicine licensees and pay much closer attention to the views of the Agreement States in this area.

Despite their "advisory" charter, the ACMUI appears to be primarily dedicated to representing the interests of the regulated community (particularly the large broad-scope academic medical centers) and seem to have the ears of at least several Commissioners for further reducing what little oversight NRC still chooses to maintain over nuclear medicine operations. The NRC has to realize that just because reduced training appears logical due to the otherwise high qualifications of the physicians at the large academic medical centers, the bulk of nuclear medicine is practiced at smaller community hospitals and "doc in the box" operations where the physician qualifications and experience are typically not up to that standard. These are the places that the T&E regulations should be written for.

E. Two response were received from this state on the third question.

First Response:

Our state does not believe that "B" is the proper compatibility designation for this rule change. As has been pointed out over and over to the states and NRC, this is a bad rule when it comes to the use of oral sodium iodide (35.392 and 35.394). This rule does not protect public health and safety, a fact that is borne out by NRC statistics. Oral sodium iodide is responsible for the majority of misadministrations as reported to NRC since 1989 - and the training requirements for use of this material have been reduced??????? Does not make sense. This was a political decision made by NRC, not based on fact. The problem is that it is a category "B" compatibility issue and if we are forced to adopt this inadequate rule to maintain compatibility, then I believe that it places our citizens in jeopardy of not being adequately protected from unqualified users of oral sodium iodide. It forces this office to do something that we all agree is wrong!!! This is a real example of where a certain physician representing the ACMUI had more "clout" than the Agreement States. Category "B" compatibility is simply wrong based on NRCs own information.

Second Response:

While I believe there should be compatibility between the NRC and the Agreement States for most rules, I am not in favor of the NRC using compatibility to force the Agreement States to adopt sub-standard rules. Most of the Agreement States adopted T&E rules virtually identical to the old Subpart J rules, even though these rules were (and still are) assigned a compatibility category "D" designation.

When the revised rules were sent to the Commissioners, that designation was changed to a "C". This made sense since the rules were being changed to be based more on the risk and past performance involved for each type of medical use (risk informed/performance based). Essentially, the new rules were viewed as representing the minimum acceptable T&E requirements for each of the different types of medical use. However, the "C" designation also allowed the states to react to problems, such as trends in medical events or misadministrations, that can be traced to T&E inadequacies.

However, there were two sections of the revised T&E that, in my opinion, were not risk informed or performance based. These sections were 35.392 and 35.394. These rules are very specific as to whom they address. They are only for authorized users of oral sodium iodide. A review of the NMED data indicated that oral sodium iodide was responsible for the vast majority of misadministrations and abnormal occurrences for unsealed source therapies since 1989. This data is incorporated in the Part G Rationale, and I encourage you to review it.

In a public meeting I explained to the Commissioners that these two proposed T&E rules did not appear to meet their staff requirements memorandum that the rules be risk informed and performance

based. I indicated that the CRCPD SR-6 Committee could not recommend adoption of these rules, but rather would recommend that prospective users of oral sodium iodide be required to meet the same T&E requirements as users of other types of unsealed sources requiring a written directive (35.390). Their response was to change the compatibility classification from "C" to "B". This does not address the actual problem.

I disagree, from a health and safety standpoint, with 35.392 and 35.394. And because I disagree with the rules, I also disagree with the compatibility classification of "B", which simply appears to be a means to try and force us to adopt rules which I believe to be inadequate.

- F. Our state does not agree with the category B designation, though there is some concern about the remote possibility of 33 different T & E requirements. Since our RAM licensing process sometimes uses the T & E evaluation of other licensing jurisdictions as part or all of the qualification of a medical authorized user, a national standard of T & E makes sense. However, our state and other Agreement States have in the past disagreed with NRC T& Es for medical applications and have effectively licensed users with different T & Es during that time. I would recommend a compatibility C for this requirement.

- G. This is okay for T&E, since many AU's move from state to state. The problem is the resolution on the amount of didactic training needed to comply with the rule. This either needs to be more clearly stated in the rule (as in Subpart J of the old rules) or through clear guidance that can be agreed to by both NRC and the Agreement States.

- H. Our state is okay with category B. The transboundry issue appears to apply here and makes sense.