UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

November 5, 1982

NOTE TO: R. E. Cunningham

FROM: John G. Davis

SUBJECT: PROPOSED REVISION TO 10 CFR 35

This proposed revision represents a significant staff effort toward regulatory improvement. The staff should be commended for its efforts thus far.

I have the following comments:

1. The impact of the proposal on the existing medical general licensees needs amplification. For example:

   - o Recognizing that few new general licensees occur each year, many physicians, clinics, entities, now operate as general licensees?

   - o It is intended that current general licensees must now apply for the standard license? If so, what is the burden of this application?

2. What are the plans for converting current specific and broad licenses to the standard license? Is it at renewal time or is it at first amendment application time?

3. On p.3 of the staff paper, the advances in nuclear medicine are discussed. Also, the "advantages of both the general and specific license types" are mentioned. The paper needs to clearly express why staff proposes the standard license approach rather than an expanded general license approach.

4. Although within the paper it is clear that the revision does have requirements not now imposed, this is not clear from the staff paper itself. This should be explained in the staff paper.

5. There should be more emphasis that the changes do not degrade safety.

6. As I understand this, the total agency resources or medical licenses regulation probably will not decrease. Rather, there will be more emphasis on safety issues and particularly on NRC time at the licensees facilities. If this is true it should be expressed more explicitly.

7. The issue on individual responsibility as compared with licensee responsibility is somewhat vague. As I understand it, unnamed individuals traditionally have used radioactive material under the supervision of named users. If this is true, why is it necessary to raise this issue?

8. The basis for the Agreement State concern should be more fully expressed. The issue appears to be whether the proposed Part 35 impacts negatively on health and safety. If we can demonstrate that it does not (or that any reduction is "acceptable") this should allay State concerns. I understand, however, that the Agreement States generally oppose this proposed rule.

9. This proposed rule runs counter to the PPG for more performance goal, rather than prescriptive requirements. This should be explained.

More specific comments are attached.

I suggest after reading my comments that staff reconsider what should be included in the basic staff paper exclusive of the attachments. It is this staff paper which will largely determine the success of the proposal.

Particularly, I think the staff paper should:

- o Clearly identify what the proposal is
  - -- a collection of pre-existing requirements
  - -- some preexisting requirements plus some new requirements
  - -- etc.
- o Emphasize why specific licensing still is needed.
- o Emphasize that safety is not degraded.
- o Describe how staff technical judgments will be applied.
- o Confront Agreement State opposition.

I will be happy to discuss this with you--preferably soon--if you believe this will be beneficial.

J.G.D.

John G. Davis

Enclosure:
As stated

cc: D. B. Mausshardt

COMMENTS ON PROPOSED
REVISION OF 10CFR35

(Comments refer to penciled numbers in right hand margin of pages.)

1. The reason for the issue on individual responsibility as compared with licensee responsibility is somewhat vague. As I understand it, unnamed workers traditionally have used radioactive material under the supervision of named users. If this is true, why is it necessary to raise this issue?

2. Suggest insertion that the NRC staff does not perform any technical review of the registration form and no license or evidence of authorization (other than the general license which is printed in the regulations) is issued by the Commission.

3. The basis for not expanding the GL in lieu of going to the standard license approach should be expanded. Extending the GL approach could satisfy the 2 stated reasons.

4. These statements could be used as the basis for an expanded GL approach.

5. The "advantages" have not been discussed.

6. What is the impact of shifting from the existing GL to the standard license approach?

7. It should be clear that an applicant that does not want a standard license can apply for a "custom" license. Do the proposed regulations specifically make this clear?

8. There needs to be expressed why the proposed approach will satisfy our concerns for safety.

9. Somewhat simplistic in expression.

10. The expression here suggests that the review is done by a computer. This needs rewriting to make clear that the computer checks for completeness (or whatever) and flags for technical review these elements of the application needing technical review. The description must make clear where the NRC technical judgments are exercised to assure safety. (They may be exercised other than in the application review process--if so, the purpose of the application, rather than registration, should be explained.)

11. Per comment 10, above, this needs further explanation.

12. Is this comparable with the 50.54 approach? If so is the "requirement" (i.e., the ability to change procedures) similarly expressed?

13. The position of the agreement states should be given.

14. Is this growth correct? 15% per year for 30 years?

15. Is a staff action taken (i.e., issuance of a piece of paper a general license) in response to the registration form? This sentence says it is (see comment 2).

16. Is this sentence correct? Perhaps it should say "Most medical institutions and physicians engaged in nuclear medicine need more . . ."

16a. What is the form of these procedures--NUREGS, REG Guides, etc.?

17. The impact of this proposed rule on the GL program needs further explanation. How many GL users are there? Do you propose current GL users must immediately apply for the standard license? Also, a better explanation should be provided for moving away from the GL. The paper should be explicit (but not defensive) over why staff proposed to move to the standard license rather than expand the GL (see comment 2).

18. Are these IE orders that place requirements on medical licensees on a continuing basis?

19. Rather than "reflects" perhaps "would correct" is more accurate.

20. "Review policy" should be "review practices."

21. These could be used as effective arguments to extend the GL rather than go to the standard license. The basis for going to the standard license needs to be expanded.

22. In view of statements at Comment 21 why could adequate protection not be afforded by a GL (or expansion of the existing GL)?

23. This is the first specific instance where it becomes clear that Part 35 is not just a collection of requirements (notes) now in other rules. The staff intends also to codify some license conditions. This should be made more explicit in the staff paper.

24. Why can't all licensees who want to use equivalent procedures do so? Perhaps, this should be expressed as, "In those cases where an applicant desires to use alternate but equivalent procedures he can apply to the Commission for consideration of his alternate procedures."

25. This currently is the approach used for safeguards procedures. Is that which you are suggesting parallel to the safeguards approach; i.e., is the regulatory expression parallel? (See Comment 12.)

26. Suggest "all procedures" be changed to appropriate procedures.

27. Rather than exempt by license conditions could not the sections that do not apply be noted in the regulations?

28. Suggest "complete descriptions" be changed to "appropriate descriptions."

29. Suggest some word other than "investigation" be used--perhaps "review."

30. Note comment 10.

31. This is first mention of use of revised Part 35 to resolve issues and petitions. The scope of what is planned should be in the staff paper.

32. See comment 18.

33. See comment 17.

34. See comment 1.

35. I don't understand this concept of "visiting authorized user." Is this intended to mean that authorized user A listed by name on Standard License X can, without NRC authorization, function as a user under Standard License Y? How is the licensee responsible for this?

36. This is an unusual expression. Actually, the corporate entity of the medical institution is the licensee--not an individual and not the mangement. This needs revision.

37. The term "may allow" rather than "would allow" may be more accurate.

38. I assume that if the licensee assumes that the collective training and experience is appropriate there is no need for a notification. Is this assumption correct?

39. I'm not certain "safest is the proper description. Rather, the ALARA program interjects the concept of reasonableness rather than the absolute of "safest."

40. Could the requirement for a quarterly review (no more or no less) allow overexposures?

41. I am bothered by designating a minimum time period for review. If the licensee wants to review more frequently is this permissible?

42. Typo - "licenseing."

43. The argument against a general license approach needs expanding. We have GL's now where there is very little enforcement action to ensure compliance. Rather, NRC action is essentially limited to responding to "events."

44. What is the basis for this statement? Does th posed Part 35 eliminate some reporting requirements?

45. A valuable addition to the package would be a listing (similar to the Derivation Table, p. 33, Encl. 1) that shows what was eliminated or changed by the proposed Part 35.

46. This is the type argument that should be advanced early in this package to counter the question of "why not a general license." (See comments, 3, 4, 17, 21, 22, 43).

47. Is this analysis available as explanation for this proposed rule?

48. "consistency" rather than "uniformity".

49. Same as comment 46.

50. Typo - "not" should be "nor". However, I'm not certain we want to say the "status quo" is not an acceptable alternative--it may not be an efficient nor effective alternative but we have been using it for many years.

51. I'm not certain the review process is "less stringent." It is done differently and at a different time (at rule issuance rather than license issuance. Rather, the term for what you propose may be "more focused" rather than "less stringent." In developing the rules you have focused on the safety requirements necessary; the screening of each application will focus on areas that need additional review.

52. Suggest "would be focused on" rather than "would be limited to".

53. Under the regionalization concept the distinction between the licensing or inspection staff will be less sharp. You may want to eliminate this sentence.

54. "Consistent" rather than "uniform".

55. A requirement (with a certificate by the licensee) for training in the procedures may help.

56. Do you have a basis for the $500?

57. I would have thought the proposed rule would be considered prescriptive rather than performance oriented (particularly 35:50; 35:51; 35:59; etc.)

58. Expression of NRC resources impact in the form of a table would aid in understanding.

59. I understand the Agreement States are, in the majority, opposed to the proposed rule. This needs expansion.

60. See Comment 4.