State of Alabama

DEPARTMENT OF PUBLIC HEALTH

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STATE HEALTH OFFICER

July 8, 1982

Mr. Donald A. Nussbaumer
State Agreements Program
Office of State Programs
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Nussbaumer:

This letter contains this Agency's response to your request for comments on NRC's proposed revision of 10 CFR 35. Our comments are offered with the understanding that 10 CFR 35 contains codes related to the use of medical radiopharmaceuticals in non-Agreement States and territories. While this matter will not be made an item of compatibility with Agreement States, it will have a significant impact on all medical licensing activities, even in Agreement States. We, therefore, offer our comments for your consideration and ask that you consider them in view of the potential impact this change will have on Agreement States.

Our comments follow:

1. Currently NRC medical licensing activities require approximately 8,850 man hours per year at a cost of $495,000. The value/impact statement to the proposed revision states that only approximately 1,130 man hours per year and a total cost of $73,000 per year will be required to implement the revision.

   Since under current NRC fee structure $107,750 of costs are recovered, does this imply that medical licensing fees will be reduced?

   Under the proposed change only 0.56 man year is required to maintain the approximately 2,631 NRC medical licenses. If the NRC considers 0.56 man year adequate to maintain approximately 2,631 medical licenses, including issuing 75 new licenses per year with prelicensing visits, will similar criteria be used in judging the adequacy of staffing Agreement State Programs during annual review?

2. Applicant's radiation safety procedures under the revision will be reviewed on a prelicensing visit by NRC licensing personnel. Currently ten hours are required to review a new application. Under the proposed change ten hours are also required, but at an increased cost due to travel, etc. It is implied that during the prelicensing visit, the applicant's radiation safety procedures would be reviewed. We question the quality of such a review under such conditions.

Many other questions arise regarding prelicensing reviews of this nature. Based on past experience, it is unlikely that more than a few applicants will have adequate procedures at the time of review. Would failure to have adequate procedures at the time of review necessitate another visit by the license reviewer?

3. If the applicant had access to an acceptable set of procedures (ie; Reg. Guide 10.8) but chose to write changes to certain sections of 10.8, or decided to write and implement an entirely new set of procedures at any time after the license was issued, the licensee would not be in violation of a license condition. Such changes would likely be detected only during inspections. To what extent does the proposed change shift current licensing responsibilities to inspection and enforcement. Perhaps your value/impact statement should address this area in more detail than simply stating that "Office of Inspection and Enforcement inspection costs may increase over present levels, if the same level of health and safety are to be maintained."

4. It appears that under the revision, procedures would only be reviewed by I & E personnel after the initial prelicensing visit by licensing personnel. Considering the fact that inspections are likely to be years apart and the fact that licensees are not restricted to an acceptable set of procedures, it appears certain that major violations of the regulations will occur and not be detected perhaps for years. Such is not precluded in the current licensing system; however, most licensees confine their operations to restrictions placed on them by management through NRC approved safety procedures.

   The reality of this potential problem appears to be strengthened by the fact that few applications currently received contain adequate safety procedures. If the licensee is permitted to change procedures at will, the changes are likely to be inadequate also. The planned revision to Reg. Guide 10.8 will certainly help in this area but not solve the problem.

   It also appears that each inspector will in reality become a license reviewer from the standpoint of reviewing radiation safety procedures for adequacy. Since the inspector will not have a copy of the procedures prior to inspection, it appears that his inspections will become more difficult also.

5. We concur with the incorporation of requirements now placed on licensees by license conditions in the regulations. We also concur with the incorporation of an acceptable set of radiation safety procedures in the revised Reg. Guide 10.8. However, we fail to see where this will add consistency to the license review process since these requirements have had the impact of regulations through license conditions for years. In fact it appears that inconsistency in interpretation is more likely to result due to the increased number of radiation safety procedure reviewers (inspectors) due to pressure put on them during the inspection. (It is an advantage for a license reviewer to place an application "to the side" and "think about it").

6. Apparently NRC's inability to "regulate" its medical general licensees is the vehicle on which this major change of direction is riding. The statements that "virtually none of the registrants notify NRC of these changes...." and "this situation makes it difficult for NRC to satisfy its inspection and enforcement responsibilities" leads one to think that major problems exist with medical general licensees and that NRC actually has an inspection program for such licensees. Based on comments of staff members during meeting, we were led to believe NRC had no such program.

   Since NRC has apparently defined this as an area of concern sufficient to justify major licensing procedural changes and since similar problems are likely to exist in Agreement States, does the NRC anticipate requiring Agreement States to develop programs to deal with the "medical general licensing problem?"

   As a point of interest we are not aware of any major problems that exist at the medical general licensee level. We are, however, aware of major problems that exist in other areas of general licensing. These have been brought to NRC's attention in the past, and the staff's response has been that no problem exists.

7. Attached is a list of specific comments regarding the revisions to Part 35. We would like to point out in the body of this letter our concern that requirements for radiation safety officers, which are listed in Part 35.900, are as minimal as they are. We are of the opinion that being registered by the American Registry of Radiologic Technologist in no way qualifies an individual to implement a radiation safety program in an institution with single or multiple nuclear medicine disciplines.

In the current draft an ARRT individual could change safety procedures, etc., without review from anyone. Such an individual may in fact have no experience with radioactive materials. This appears to violate the requirement in 10 CFR 30.33(a)(3).

8. Since only one supplier of general licensed material exists, wouldn't it be a simple matter to obtain a current list of this supplier's customers, from which NRC's general licenses could easily be updated?

9. In the draft to the Commissioners from William J. Dircks the following statement appears: "The staff proposes to simplify the licensing process for medical licensees by transferring all requirements for human uses of by product material from all sources to 10 CFR Part 35." This statement implies that an applicant or registrant could simply turn to 10 CFR Part 35 and discover all requirements pertaining to medical licensing. Such an interpretation would, however, be incorrect as is clearly defined in 35.1 Purpose and scope of the proposed changes. The term in the statement above "from all sources" is misleading to the casual reviewer.

10. We would like to request that you reconsider your proposed plans to eliminate a review of physician qualifications to practice nuclear medicine. Verifying physician qualifications could not increase the cost of licensing significantly while at the same time provide some reasonable assurance to the license writer that users of radioactive material were qualified. The present method leaves interpretation of "qualified" solely up to the physician. This applies specifically to non-certified physicians.

In summary, this Agency commends NRC Staff for seeking ways to simplify the licensing process and to reduce our common problem of "paperwork." We agree with the philosophy of placing Reg. Guides and license conditions, which have the authority of regulations, in the regulations. This is a positive step. We are, however, concerned with the procedure for implementing the proposed change and the impact such changes will likely have on this Agency's licensing and inspection program.

Thank you for providing us with the opportunity to comment on the proposed changes.

Sincerely,

Aubrey V. Godwin, Director
Division of Radiological Health
Environmental Health Administration

AVG:KEW:mpw
Attachment

SPECIFIC COMMENTS ON
PROPOSED CHANGES TO 10 CFR 35

1. 35.17(b). If no review of a physician's qualifications is required by NRC, why delay a physician from practicing nuclear medicine until his name is added to the license by amendment. If the form is completed (checked properly), isn't approval granted? Are improperly checked forms anticipated?

2. 35.51(e). The requirement that survey meter calibration records be maintained idefinitely appears to be unwarrented in light of other records which can be disposed in one or two year periods.

3. 35.51(a). Medical licensees under our jurisdiction are encouraged to have even their GM survey meters calibrated on an annual basis. We note that 35.51 does not require that any survey meter other than an ionization chamber instrument be calibrated except on receipt and following repair.

4. 35.53(b). Does this section imply that a licensee must assay 1.0 microcurie cobalt 60 schillings test caps before administering to patients? Will new "generally licensed" (Group I) licensees be required to have dose calibrators? If so, has this economic impact been evaluated?

5. 35.59(b)(1). Under the revised criteria any licensee could leak test any medical sealed source without his procedures or equipment having been reviewed by anyone. As currently written an ARRT technologist with no experience in handling radioactive material could serve as the licensee's radiation safety officer. This individual could then be responsible for measuring leak test samples "in a manner to detect the presence of 0.005 microcuries of radioactive (by product) material." Leak testing should be specifically approved.

6. 35.70. Perhaps a difference in philosophy exists as to the purpose of surveys in restricted areas. We recommend to our licensees that surveys be performed during work periods and not just at the end of each workday. Surveys performed at the end of each workday do not incorporate the ALARA concept.

7. 35.70. Under the proposed change such surveys are likely to be made with survey meters calibrated when received, which could mean years ago. ALARA should justify specified calibration intervals.

8. 35.17(a). This section appears to be incomplete as far as sentence structure is concerned.

9. 35.35 and 35.80. Are two separate sections needed for mobile services?

10. 35.304 and 35.405. These sections require the authorized user to provide written radiation safety instructions to all persons caring for the patient. Should not this be the responsibility of the RSO? Should not such procedures be approved by the Committee? Are the "authorized users" instructions binding on other personnel in an institution? Does each authorized user develop his own procedures?

11. General Comment: the proposed changes in several different locations contain statements such as "the Radiation Safety Officer shall" or "the authorized user shall." Since the Radiation Safety Officer and the authorized user are not necessarily the licensee, shouldn't the phrases be prefaced somewhere in the document to place the ultimate responsibility for assuring that these functions are carried out on the licensees management?

    Example: What happens if the RSO fails to perform surveys? The regulations assign that responsibility to the RSO. But the RSO is not the licensee. The functions are not assigned to the licensee.