CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
2600 Bull Street, Columbia, South Carolina 29201

October 7, 1982

G. Wayne Kerr, Director
State Agreements Program
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Wayne:

I have enclosed a summary of comments on the proposed revisions of 10 CFR Part 35 prepared by the Conference of Radiation Control Program Directors, Inc.

Although NRC has stated that the Part 35 revisions would not be made an item of compatibility, certain changes will be "strongly recommended" to the Agreement States and have the force or impact of compatibility. We ask that you consider our comments in view of the potentially significant impact the Part 35 changes will have on programs in Agreement States, as well as non-agreement licensing states.

The Conference commends the NRC staff for seeking ways to simplify the licensing process. In addition, the philosophy of placing Regulatory Guides and license conditions in the regulations is seen as a positive step. We are concerned, however, with the procedure for implementing the proposed changes and support those concerns with the attached list of specific comments, as well as the major concerns outlined below.

Our foremost concern is the elimination of the pre-licensing review of radiation safety procedures. Under the revision, it is implied that during the "timely" post-licensing inspection, the applicant's radiation safety procedures would be reviewed. Since many applications currently received do not contain adequate procedures, it follows that few will have adequate procedures at the time of the post-licensing inspection. The question arises: Will this necessitate another visit by the license reviewer?

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In addition, it 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, not only will inspections be more complicated but the quality of the review would be more questionable. It is felt that inconsistency in interpretation is likely to occur due to the increased number of reviewers/inspectors and to increased pressure during inspections.

The NRC inspection and enforcement role is said to be concerned with whether or not the requirements in the regulations are met, not the details of the procedures used to meet them. We question how this will be done in reality. It seems that an excess of subjectivity will be involved, and what may be adequate in the licensee's opinion (e.g., procedures) may not be adequate in the mind of a particular NRC inspector. In that case, it appears that the licensee would be cited for operating a radiation safety program in good faith. At the present time, most of the subjective content may be corrected during the license application review process.

Because interpretation difficulties are inevitable, a procedural plan, known and agreed-upon beforehand by both the NRC and the licensees, should be developed.

Overall, the theory behind the proposed Part 35 is good; however, the revision includes what appears to be many subjective requirements with present objective program specifications deleted.

In closing, it should be stated that many agreement states do not have the funds nor the mechanism to try such a concept unless it will (a) provide to require few changes in the regulations, (b) not require expensive equipment to process, (c) save personnel time and (d) not compromise the radiation safety of the employees and the general public.

I would appreciate being kept informed of developments in this matter.

Thank you for providing us with the opportunity to comment on the proposed changes. Should you have any questions, please contact me.

Sincerely,

Heyward

Heyward J. Shealy, Chairman
Conference of Radiation Control
Program Directors, Inc.

HJS:cc

cc: Charles M. Hamlin
Executive Board
Federal Liaisons

referenced in Enell 1.25.94 memo comments on rev

Summary of
Comments on the Proposed Revision
to 10 CFR Part 35

✓35.2(a) Is a reference to an "Agreement State" appropriate? Aren't these regulations only applicable to NRC activities and not those of Agreement States?

✓35.15 "Visiting Authorized User". This definition is unclear and may be confusing to licensees.

O35.17(a) What is meant by a "method" of human use? see SofC

O35.17(b) If the NRC must approve each authorized user, why must the Radiation Safety Committee have to approve the user when its authorization really carries no weight? (Reference: 35.31(b)(2)) see SofC

O35.17(c) May an authorized user on a license become the Radiation Safety Officer without notifying the NRC? If not, this section should be changed to read "...not listed on the license as the Radiation Safety Officer to perform..."

✓35.17(e) A license amendment should be obtained before using radioactive material at <u>any</u> new location not identified in the license, not only those where a mobile nuclear medicine service will be supplied.

✓35.17(f) This section is very subjective - what may not be a significant change affecting radiation safety in the mind of the licensee may be significant in the mind of the inspector. (The NRC may have to outline specific guidelines or be willing to accept differences of opinion.)

35.18 (Reference: General introduction and discussion of rationale for 35.18 and 35.18 Notifications)

O What happens when an authorized user is no longer present? The general rationale discussion is not clear on this point, and it could be interpreted that the NRC would let a hospital keep operating (hopefully not).

O Would a hospital have to notify the NRC when one of ten authorized users permanently discontinues performance of duties under the license (hopefully not).

<u>Notifications</u>. "The licensee shall notify the Commission in writing...within thirty days when an authorized user, R.S.O., or..., permanently discontinues performance of duties under the license."

The notification requirement (within 30 days) of the resignation of the Radiation Safety Officer is good and appears to be consistent with what happens in actual practice. However, what

35.18 (cont.) ○ happens at the end of 30 days and the licensee has no Radiation Safety Officer? In addition, it seems appropriate for the reporting requirement to include "leave of absence", "sabbatical" or "discontinues full-time performance" when considering the duties of the Radiation Safety Officer. see Sec C for intent

35.29 ○ "Specific exemptions".

This section is good and will allow flexibility and practicality.

35.31(a)(4)(vi) ✓ How extensive must ALARA program reviews be? What minimum documentation is required?

35.31(b)(2) ○ See comment for 35.17(b) above. see Sec C

35.34(c) ✓ The written permission should be maintained for two (2) years after the final date of work by the visiting authorized user in the hospital.

35.38 Supervision (a) "The authorized user supervising the unlicensed receipt, possession, use..." n.a. - for early draft

It is assumed that "unlicensed" is a typographical error.

35.38(a)(1) ○ What is meant by "supervised individual"? Another physican not listed as an authorized user, a technical individual or both? How does the training required here vary from that required in 35.32(b) or is it a duplication?

35.49(a) ○ Should distribution be defined? (Reference: Controversy over whether or not hospital A can transfer the remaining portion of a radiopharmaceutical in a multidose vial to hospital B.) defined in Part 32, not here.

35.50 ✓ It appears that many of the specifications included in Regulatory Guide 10.8 have been deleted here; e.g.,

- Number of calibration sources needed
- Energy specifications
- Acceptable percent agreement between measured activity and calculated activity
- Required repair of instrument
- Etc.

It is suggested that the National Bureau of Standards and the Bureau of Radiological Health, Nuclear Medicine Laboratory, Cincinnati, Ohio, critically review this section.

35.50(a)(4)(c) "The licensee shall mathematically correct readings for any error in excess of 10 percent..."

A requirement for repair or calibration in addition to mathematical corrections seems appropriate for errors in excess of 10 percent. The October, 1980, Revision 1 to

35.60(a)(4)(c) (cont.) U. S. NRC Regulatory Guide 10.8 suggests variations greater than ± five percent indicates the need for instrument repair or adjustment.

35.51 Many of the specifications contained in Regulatory Guide 10.8 have been deleted or changed in this section.

35.51(a)(2) "Calibrate other survey instruments on receipt and following repair."

A mobile service survey instrument is often carelessly used and/or transported which may affect calibration. The annual calibration requirement is felt to be necessary for instruments being transported.

35.51(c)(2) What if a GM instrument cannot be calibrated to read within ± 20 percent?

35.51(e) The known accuracy and activity of the calibration source is important information. This section outlines no requirements for the specifications of the source to be used for calibration.

35.51(f) It is recommended that this section be worded to require that quarterly readings of check sources be maintained.

It is suggested that the National Bureau of Standards critically review this section.

35.53(b) A record must be maintained of calibration of doses less than 10 microcuries, their lot number and their expiration date. Such a new requirement appears to be inconsistent with NRC's rationale for rewriting 10 CFR 35.

35.53(c)(2) "Keep a record of measurements...the record must contain... patient's name and identification number."

Recording patient identification is appropriate; however, hospital administration should be responsible to decide how this is to be accomplished.

35.58 "Any person licensed...may receive, possess and use...sealed sources...if such sources do not exceed 5 millicuries each."

Experience has shown that it is not unusual for reference sources to be lost or for leak tests to show greater than 0.005 microcuries of contamination, thereby reinforcing the need for requiring six-month leak tests and quarterly inventories.

35.59(c) "To satisfy the leak test requirement the licensee must (3) ...measure the sample..."

From experience, many licensees are not able to accurately analyze leak and wipe tests. The fact that these procedures will not be reviewed prior to license issuance is a concern.

35.59(d) "The licensee shall keep leak test records for three years. The records must contain the model number and serial number of each source tested..."

Since iodine-125 has not specifically been exempted under 35.59(f), it appears that in the event that iodine-125 seeds must be leak tested, the licensee would automatically be in noncompliance as no serial number is available on these sources. The iodine-125 shipping document appears to contain the model number and lot number only.

35.60 Paragraph (a) states that material shall be kept in radiation shielded syringes. Paragraph (b) states that material can be used outside the shield. Which one applies? Can't do both.

35.62 Syringe labels. "Each licensee shall conspicuously label each syringe radiation shield which contains a syringe with the radiopharmaceutical to be administered..."

An exemption from labeling should be provided for any shield containing a syringe with a radiopharmaceutical that is to be administered immediately after preparation.

35.70 "Surveys for contamination and ambient radiation exposure rate."

(a) "...survey...at the end of each day..."
(b) "...survey...at leas. once each week..."

No distinction has been made between wipe surveys for contamination and surveys for ambient radiation exposure rate. Without clarification, it is doubtful that the intent will be met.

Surveys made at the end of each day are not consistent with ALARA. If nobody is present at night, what is being protected? What are the hazards while people are working?

What is the definition of a low-range survey meter (i.e., type, range, window thickness, etc.)?

Can an individual check for contamination in the area of the generator and storage area with a low-range survey meter? The meter cannot distinguish contamination from "background" from generators and stored material. This comment has been made on several occasions.

35.75 Release of patients containing radiopharmaceuticals or permanent implants.

"The potential for detrimental effect of an unnecessarily long nospital confinement" is not seen as a prudent judgment for allowing a 500 millirem or greater whole body dose equivalent to a co-worker or family member.

35.75 (cont.) Under this new criteria, how is hospitalization determination made? Do you wait for the thyroid to concentrate iodine-131 and make measurements or do you perform a survey immediately after administration?

This section does not appear to be feasible and is not consistent with 20.105.

35.92 Decay-in-storage. "A half-life of 65 days was chosen as the decay-in-storage half-life cutoff limit because storage in excess of 10 half-lives or 650 days is more appropriately considered as an interim burial."

Although storage in excess of 650 days may be "more appropriately considered as an interim burial", it simply appears that another name has been given for "decay-in-storage" to preclude the "Catch-22" nature of 35.92, i.e., cobalt-57 or selenium-75 could be held for "interim burial" prior to disposal but could not be considered as stored for decay. Perhaps a definition of "interim burial" should be provided for clarification if this is not the case.

35.300 General comment: A section is included giving instructions for release of patients containing sealed sources but no section is included for release of patients containing material listed in 35.300.

Is such equipment necessary if services are performed by consultants? Has the cost been considered? Has the training of licensees in calibration procedures been reviewed?

35.304(a) "The authorized user shall provide oral and written radiation safety instructions...etc."

Does this eliminate the Radiation Safety Officer from giving instructions?

35.400 "The authorized user or supervised individual shall use... etc."

Can a supervised individual "use" radioactive material? Isn't the "authorized user" responsible when material is used under his supervision?

35.500 Comments of 35.400 above apply.

35.604 "This includes...plans and elevations...etc."

Are "elevations" being requested?

35.606(g) "Allowing...on the licensees to perform..."

It appears that the word "licensee" is omitted.

35.610 Since the major concern in such an emergency is the removal of the patient from the room and securing the room, it is recommended that requirements for such be included in the regulations and not in a guide or license condition. It's more important to remove the patient than to know the Radiation Safety Officer's phone number, which must be included in (c). Why not include 35.633(h) in this section?

35.630(a) "The licensee shall have a calibrated dosimetry system available for use."

In the past dosimetry systems have been provided, to a large degree, by consultants who have the equipment. This condition now requires each licensee to have such equipment.

35.632(a) "Any licensee authorized to use a teletherapy unit for treating humans shall perform full calibration measurements on each teletherapy unit."

Does this literally mean that the licensee must do this? Can a consultant perform such services? Who trains licensees in calibration procedures?

These comments apply to other paragraphs of 35.632.

35.632(f) Section 35.632(a) states that the licensee shall perform calibration procedures. Section 35.632(f) states that it must be done by a "qualified teletherapy calibration expert."

The two should be consistent. Which one applies if the licensee is not a qualified teletherapy calibration expert?

35.633 Again, this requires the licensee to perform this service. The licensee may not be qualified. 35.633(d) permits this. Is training not required? Many patients can be treated in the 15-day review period allowed by 35.633(e).

35.641 "Prior to...source, the licensee shall perform radiation surveys...etc."

Are consultants being eliminated from performing such services? Or do licensees have to perform such tests in addition to consultants if consultants are used?

35.641(a)(1) General comment: Are such measurements taken with the collimator open or closed? Significant differences in the plan of the source-collimator exist with the collimator closed as opposed to being shut. There exists confusion among "qualified experts" as to how this survey is to be performed.

35.641(a)(2)(i) Should not ALARA be applied in this section or at least a reference to ALARA.

35.900(d) This requirement is good but it may not always be appropriate. It may be advisable to include some words, such as "or equivalent" in this section to allow for an exception, if needed.

35.900(e) "continuing involvement".

Again, this is a subjective requirement and may be an area of legitimate differences of opinion between a licensee and a NRC inspector.

35.920 Training for imaging and localization studies. Can the 200, 500 and 500 hours of training be acquired concurrently (or any portion)?

35.931 Training exemption for therapeutic use of radiopharmaceuticals. 35.300 appears to be combining Groups IV and V; however, the exemption does not specify for which type of radiopharmaceutical therapy the physician previously had to be licensed. It appears that the physician could have been licensed just for I-131 for hyperthyroidism and then qualify for all of 35.300.

35.940 Training for therapeutic use of brachytherapy sources. No grandfather clause.

35.941 Training for ophthalmic use of strontium-90. No grandfather clause.

35.960 Training for teletherapy. No grandfather clause. Can training be acquired concurrently?

General Comment

Two of the specific materials licensing objectives are proposed to accomplish a reduction in the regulatory and administrative burden on the regulated industry and to improve records management.

When considering the varied and scattered record retention requirements, it appears that a uniform retention time, excluding personnel dosimetry records, could be determined to better meet this goal.