Walker

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

Ref: SA/LAB

OCT 18 1982

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety, NMSS

FROM: G. Wayne Kerr, Director
Office of State Programs

SUBJECT: CONFERENCE COMMENTS ON PART 35 REVISION

Enclosed is a copy of a letter from the Conference of Radiation Control Program Directors, Inc., (CRCPD) providing comments on the August 31, 1982 revision of the Part 35 Revision.

The CRCPD is an organization whose members are Agreement State and non-Agreement State radiation control program directors. We share their concerns and request that you consider them and specifically discuss them in the Part 35 Commission Paper.

G. Wayne Kerr

G. Wayne Kerr, Director
Office of State Programs

Enclosure:
As stated

cc: William Walker, MLB

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.

(1) 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?

(2) 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.

(3) 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.

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

(5) 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.

(6) 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 compromist 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 G. Shealy, Chairman
Conference of Radiation Control
Program Directors, Inc.

HGS:bo

cc: Charles M. Hardin
Executive Board
Federal Liaisons

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.

35.17(a) What is meant by a "method" of human use?

35.17(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))

35.17(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)

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).

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.

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.

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..."

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.)

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

35.50(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 6 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 least 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 hospital 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.

re Kerr/CRCPD cover letter major concerns:

2. If, in the opinion of the inspector, the licensee has not developed adequate procedures, the NRC would schedule a ~~second~~ follow-up inspection. The licensee would bear the cost of both inspections. The potential expense of a second inspection should serve as an inducement for the licensee to have adequate procedures prepared before submitting the application. ~~See~~ See 4. below.

2. The staff has included in the proposed regulations those program components that, in its judgment, are ~~critical necessary for the~~ critical to ensure the safe use of byproduct material in the medical environment. Furthermore, 1. The ~~philosophy of the extent~~ purpose of inspection should be to ensure that critical standards are indeed being met, not to ensure that instructions for compliance with those standards have been written.

3. There may be an increase in the amount of ~~subjectivity~~ professional judgment used by the inspector. The staff feels that this is a ~~secondary~~ realistic price to pay for the licensee for the privelege of being authorized to ~~edit~~ update procedures without having to request a license amendment. The good faith of the licensee is ~~irrelevant.~~ secondary to that condition for protecting public health and safety.

4. There are now, always have been, and will continue to be difficulties in misinterpretation. ~~From this, the staff feels~~ The staff will develop a procedural plan, and invites CRCPD comments. Regulatory Guide 10.6 has been revised to include procedures acceptable to the staff for ensuring compliance with the proposed regulations.

5. The staff feels that the "objective program specifications" may be so specific as to not be suitable for inclusion in the regulations. The requirements that were included are not subjective, they are well founded in the safety literature. } rewrite clarify

6. If an agreement state regulates the industry by license condition in addition to a code of regulations, the ~~reg~~ regulations would have to be revised before implementing the proposed licensing system. The system is suitable for manual ~~or~~ or machine processing. The system will save personnel time. The staff does not feel that the radiation safety of the general public or employees will be compromised.

Kerr / CRCPD letter summary of comments:

35.2a This ~~regulation~~ section was drafted by ELD. If it did not include the reference to Agreement States, ~~medical~~ human use licenses issued by those states might appear to be invalid.

35.15 Several individuals have reviewed the definition. Even those who are unfamiliar with the concept recognize the intent of the definition.

35.17a The word "method" is generally defined as "a procedure or process." The word method was chosen because the word procedure ~~was~~ is ~~might be confused with its~~ sometimes used in the medical environment to refer to a specific event rather than to a series (as in "We did the procedure on Mr. Jones.") of steps.

35.17b The NRC bears the final responsibility for authorizing ~~individuals~~ persons to use byproduct material.

35.17c This wording allows an authorized user listed on the license to assume the duties of the RSO in the case of incapacitation of the latter.

35.17e The wording was chosen to make it clear that ~~the NRC~~ a mobile service licensee cannot deliver service to a client without the approval of the NRC. To use more general wording would have implied that the nuclear medicine service in a hospital could not move its preparation or injection area with NRC approval. The NRC will identify on each license the street address of each authorized location of use.

35.17 f The staff acknowledges that the section is vague. The sub-section was included because the staff recognizes that there may be program changes other than those identified in sub-sections (a) through (f) that might have a significant impact on safety.

35.18. 1. The license will ~~be~~ authorize, ~~such~~ for example, "human use of byproduct material identified in §35.200 by, or under the supervision of, Dr. John Smith." If Dr. Smith is the only ~~authorized user~~ individual ~~listed for~~ ~~on~~ license ~~as~~ an authorized user ~~for~~ the byproduct material listed in §35.200, in his absence such material could only be used by, or under the supervision of, a visiting authorized user. ~~Use by any~~ Any other use would not be in compliance with the license and the regulations.

2. Yes.

3. —

4. Other individuals listed on the license should assume the responsibilities of the RSO pending his replacement. If the licensee does not promptly replace the RSO, the NRC will consider ~~action~~ follow-up action. The staff considered specifying a certain number of days, and welcomes further comment on this section.

35.29 Thank you

35.31a4vi The staff welcomes comments on the extent of program reviews. The staff considered such things as personnel exposure reports, survey reports, and levels of use. ~~torts~~ However, the staff felt that to include a list of items might lead licensees to assume they had met the requirement if they had checked ~~they~~ only the items listed. The only documentation required is the summary of deliberations that is contained in the meeting minutes.

35.31b2 The NRC would ~~probably~~ not authorize an individual for human use if the licensee's Radiation Safety Committee did not feel the individual could safely handle byproduct material.

* 35.34c The comment will be incorporated.

35.38 Since the technologist or physician who is supervised is not listed on the license, that individual's receipt of byproduct material is unlicensed. This is not a typographical error.

35.38a1 Any individual who is not listed on the license but who handles byproduct material must be supervised. ~~It~~ This may be a physician or a technologist. No training is required.

35.49a A ~~neighbor~~ licensee hospital is not authorized to ~~distribute~~ receive unused material from a neighbor hospital for human use. because it has not been distributed (by the neighbor hospital) pursuant to Part 30 and Part 32. The staff agrees that the word distribution should be defined in the regulations, but ~~this~~ formulation of a definition for this word was not part of the task force mandate.

35.50 The National Bureau of Standards and the Bureau of Radiological Health will be asked to comment on the proposed regulations.

35.50 ~~a.1.c~~ The staff agrees that ~~not~~ a dose calibrator an error in excess of 10% should be repaired. However, in many cases, mathematical correction will provide for acceptable measurements with less ~~negative~~ impact on patient care. The staff welcomes more comment on this matter.

35.57 The staff welcomes more comment on this matter.

35.57 a 2 The current draft of the proposed regulations requires that each instrument be calibrated annually.

35.51 c 2 If an instrument cannot be calibrated to within 20% accuracy it cannot be used to meet ~~the~~ requirements of the proposed Part 35. A ~~majority~~ portion of the staff felt that it is acceptable to use a survey instrument that is inaccurate in excess of 20% if a ~~calibration~~ correction chart or graph is attached. The staff welcomes further comment.

* - Section that must be revised to reflect the comment. W. Hess NMSS

* 35.51 e Bill - an entire paragraph that describes recordkeeping for survey instrument calibration has been excised. Where did it go?

35.51 f Good point

35.53 b This was included to parallel a recent separate rulemaking. The staff feels that a record should be kept for each administration of byproduct material.

35.53 c 2 Some misadministrations ~~due~~ are the result of two patients having the same names. The staff feels that recording ~~the~~ each patient's identification number will reduce the probability of such a mistake.

35.58 Any licensee who receives a sealed source must comply with §35.59, "Requirements for possession of sealed sources." Bi-annual leak tests and quarterly inventories are required ~~therein~~ in that section.

35.59 c Instructions for leak testing ~~sealed~~ sources and analyzing wipe samples have been appended to Regulatory Guide 10.8, ~~which~~ Revision 2, which will be published for comment with the proposed revision of Part 35.

* 35.59 d The comment will be incorporated.

35.60 Subsection (a) requires that material "to be administered..." (future tense) be shielded. Subsection (b) requires the use of a shield during administration except in those cases in which use of the shield would compromise the injection.

35.62 The staff disagrees. Even in a clinic with a small patient load and only one technologist, the possibility of transposing two dosages is present. The staff does not feel that the requirement is burdensome.

35.70 (1) The section has been reworded to require a daily exposure rate survey in the clinic, a weekly exposure rate survey in the ~~waste~~ storage areas, and a weekly ~~contamination~~ removable survey in the clinic and storage areas.

The purpose of the subsection is to require

(2) a survey at the end of the day ~~with~~ to ensure that no byproduct material has been left ~~out~~ unsecured. The staff agrees that exposure rate surveys during the work day ~~may be~~ are useful. ~~However, staff experience in t and interviews with licensees have indicated that~~

(3) A low range survey instrument is one that detects individual photons rather than exposure rates. It ~~may be~~ must have either a GM or Na I (Tl) detector. The staff did not feel that ~~a type~~ instrument specification was necessary or appropriate for inclusion in the regulation. More description has been included in the proposed revision to Regulatory Guide 10.8.

(4) The section has been rewritten to require both exposure rate and removable contamination surveys.

Call Donna Doerock (Colorado) 303 629 1818
re followup to AJHP 1978 article

35.75 In arriving at the release limit the staff assumed that I-131 therapy patients present the greatest hazard to a co-worker or family member. Current NRC license conditions allow for release of patient when the body burden is 30mCi or less. This would result in an exposure rate of about 6mR/hr at one meter. In a study of the thyroid and whole body dose equivalent exposure of seventeen family members of seven I-131 patients & (AJHP v68 n3 pp225-230, March 1978). the highest thyroid dose equivalent to a family member was estimated to be 1.3 rem; fifteen of the seventeen were less than 0.3 rem. Ten family members were issued TLD badges. The maximum whole body dose equivalent for a family member was 2.2 rem; the nine other whole body dose equivalents were less than 0.16 rem. [Insert NCRP37 recommendations.] The staff does not believe the financial and emotional expense of a longer hospitalization is warranted. Section 20.105 regulates possession, use, and transfer by a licensee. The act of administration to a patient completes a transfer. After material is administered, the patient possesses the material. The patient is not a licensee, and therefore is not subject to §20.105. The staff feels that an exposure rate measurement is easier, safer, and more relevant than an estimate of whole body burden.

Include something about internal exposure and effective $ of patient.

35.92 The staff did not intend to invent a new word. Under the proposed procedure, Co-57 would have to be stored 2700 days, or ~~over~~ seven years and five months; ~~colonium-~~ Se-75 would have to be stored for 1200 days, or three years and three months. The staff has made a judgment that the sixty-five day half-life limit will provide for significant ~~regulatory~~ financial relief to the industry without endangering workers or the public. The industry has not shown the need or safety rationale for further relief.

35.300 Release of all pharmaceutical patients is regulated by § 35.75. A ~~special~~ section ~~for be~~ regulating the release of brachytherapy patients was included in ~~§§~~ Subpart D because there are special safety procedures (source count) that do not apply to pharmaceuticals.

35.304/a The authorized user is responsible for ensuring that the instruction is given. The Radiation Safety Officer may give the instruction.

35.400 and 35.500 A supervised individual can use byproduct material. The ~~an~~ supervising authorized user and the licensee are responsible for the safe use of the material. ~~If~~ The authorized user should not release byproduct material to a supervised individual unless assured that it will be used safely.

35.604 Elevations of a teletherapy room are needed if areas above or below the room are unrestricted and accessible.

35.606g The mistake has been corrected

35.610 The staff feels that site-specific instructions should be developed for each teletherapy installation; therefore, a specific procedure was not included in the regulations. The names and telephone numbers are required so that the technologist can immediately contact a responsible individual who has the administrative authority to order that the facility be secured pending repair. Door interlocks were not included in this section because they are not normally used to interrupt the teletherapy beam. Therefore, the failure of a door interlock would not normally be noticed by a technologist.

35.630a and 35.632a and 35.632f This regulation does not require that the licensee possess a dosimetry system. A dosimetry system must be available for use. It may either be on hand or available through a contract service. Similarly, an employee of the licensee or a consultant may perform a calibration. The licensee is responsible for ensuring that the calibration is done.

35.633 Spot checks may be performed by a technologist. If the technologist cannot follow the procedures established by the qualified teletherapy calibration expert, then the expert would have to perform the spot check. The staff feels that the fifteen day review period is as stringent as possible without interrupting or dramatically increasing the cost of patient care. The staff welcomes comment on this time period.

35.641 Only one survey need be performed. The licensee is responsible for ensuring the survey is done. A consultant may do the survey.

35.641a1 The staff welcomes comment on whether the collimators should be open or closed

35.641a2i The staff feels that the ALARA statement contained in §20.1(c) is sufficient.

35.900d and 35.900e The ~~comment~~ regulation has been revised to require that the Radiation Safety Officer have had the equivalent of one year of full time employment in medical radiation safety within the last five years. The phrase "continuing involvement" has been excised.

35.920 The authorized user must have completed 1200 hours of instruction.

* † 35.931 The comment will be included. Bill - Klucsik says we can insert a reordering of sentence 35.34(a)3 here after the effective date phrase of 35.931 to meet the problem. The intent, however, must be clearly reflected in SC p 32. We will need the same fix in 35.911 and 35.921.

* † 35.940 and 35.941 and 35.960 A clause will be included Bill - if there is a single one-method-of-use brachytherapy practitioner out there, we will have to grandfather him

35.960 The authorized user must have completed 1170 hours of instruction.

General Comment: The clever manager will, when creating a record, refer to the regulations to see what must be included in the record. The retention period is listed in the same place as the content requirement. The retention period can be noted on the record.

† Bill - I have prepared new grandfather clauses and forwarded them to Klucsik for markup rdm 12-08-82