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

SEP 30 1982

MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

Robert B. Minogue, Director
Office of Nuclear Regulatory Research

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

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

The enclosed Commission paper is forwarded for your approval and for transmittal to the Executive Director for Operations (EDO) recommending Commission action. This proposed rule making is a complete revision of 10 CFR Part 35, Human Use of Byproduct Material. A streamlined licensing procedure, for medical applicants, based on the proposed rule, is also detailed in the paper. The significant benefits of these proposed actions for NRC, its licensees and the public are addressed in the paper and the Value-Impact statement (Enclosure 3).

All affected NRC offices, including the regions, were represented on the task force which developed the proposed rule. The task force was headed by Dr. William Walker, Medical and Academic Licensing Section Leader, Office of Nuclear Material Safety and Safeguards (NMSS). Major contributions to the paper's development were made by Norman McElroy and Deborah Bozik from the Office of Nuclear Regulatory Research (RES).

Release of the proposed action (for public comment) has the concurrence of NRC offices affected by its implementation. The Office of State Programs (SP) and the Office of Inspection and Enforcement (IE) have expressed some reservations about specific aspects of the paper.

The Office of State Programs is not opposed to publication of the proposed rule for public comment at this time but expressed a concern shared by several Agreement States. Although these states did not express disagreement with the revised rule, they favor the current

practice of a labor intensive review of specific procedures submitted by the applicant. Continuing this practice would nullify much of the beneficial aspects of the proposed revisions. The staff feels that little or no enhancement of safe operations is achieved by such a detailed review of procedures when regulations are explicit enough to provide a functional framework for the licensee's development of such procedures.

The Office of Inspection and Enforcement concurs with the intent of the proposed rule but, has expressed concern about paragraph 35.2(b) and its exemption from the requirement to possess a license for those individuals who receive, possess, use or transfer byproduct materials under the supervision of an authorized user named on the license. These individuals would however still be required to comply with all other provisions of Part 35. IE feels that the current regulation which implies that issuance of the license bestows on the licensee the responsibility to ensure that its employees conduct their work safely and in accordance with the license is adequate. Public comments about this provision will be carefully considered by the task force in consultation with the IE staff in resolving this conflict.

Extensive contacts were made with medical groups in the process of developing the rule. These have included NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), the Society of Nuclear Medicine (SNM), American Association of Physicists in Medicine (AAPM), Health Physics Society (HPS) and individual physicians and physicists. The vast majority of comments have been favorable.

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

Enclosure: Commission paper

Texas Department of Health

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Commissioner

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rec'd 3/28 pbm

March 20, 1985

Docketing and Service Branch
Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Sir:

Thank you for the opportunity to comment on the preliminary proposed revisions of 10 CFR Part 35.

Bureau of Radiation Control staff have reviewed the documents and offer the following comments for consideration:

General Comments

1) The major concern with the proposed rules continues to be the amount of technical review of the applicant's procedures or procedural revisions prior to the issuance of a license or an amendment. Our licensing experience has shown that in at least 40 percent of all medical license applications, more information must be requested of the applicant prior to license issuance. The deficiencies in the application are, for the most part, due to the applicant's lack of technical expertise or errors in judgement. The proposed rules provide few pre-licensing mechanisms to determine deficiencies in the proposed radiation safety program.

2) We find that formalizing existing policies into regulations is better from a legal standpoint than having them stated in guides or other documents. As a matter of practicality, however, the rules should be made up of only those procedures which, with very few exceptions, apply to all licensees of that category. In several cases the proposed rules did not allow the flexibility of current licensing practice, and many exemptions in the form of license conditions would be necessary to cover those situations. Examples are discussed in the Specific Comments section.

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3) Shifting the burden of review of procedures and procedural changes to inspectors will not result in an effective use of regulatory time. Inspecting by approved procedures is demanding enough without the additional responsibility of making on-the-spot determinations of adequacy of procedures and making lengthy explanations to the licensee. While all inspectors should have judgement capabilities for with this duty, consistency among inspectors may be difficult to achieve.

   In addition, non-compliance items pertaining to adequacy of procedures will not be determined until months to years after the fact.

4) Unless model procedures incorporate ALARA principles, a licensee may not be inspired to incorporate a separate ALARA program. In addition, ALARA procedures should be practiced by both hospital and private practice facilities.

5) The group system of licensing has worked well for many years. There appears to be no valid reason for converting to a new "type of use" system. This change will be confusing to current licensees and to Agreement States who pattern their regulations after those of the Nuclear Regulatory Commission (NRC). The NRC should add new groups if such are necessary but should retain the present system of Groups I-VI.

Comments on Specific Sections of Proposed Rules

35.33 The section on the authority and responsibilities of the Radiation Safety Officer should clearly specify authority to suspend operations believed unsafe.

35.34 Sixty days seems excessive for visiting users covering vacations and illnesses. Since the name will not appear on the license, a pharmacist cannot verify that the individual is, in fact an authorized user at the facility.

   In practice, Texas inspectors have experienced difficulty with visiting user authorizations.

35.36 This needs to be carefully qualified. Locations and use areas for generators, brachytherapy sources and therapy solutions should not be allowed to be changed prior to review and authorization by the Commission. Proposed use and storage areas do not always reflect good judgement, and allowing the licensee to change his procedures would only work at large hospitals with a truly working committee.

35.51 This section does not allow for calibration of survey instruments by outside commercial firms.

35.53(a) The requirements for assay of radiopharmaceutical dosages should specify the acceptable limit (10%).

35.59 This section appears to authorize analysis of leak tests only instead of collection of wipe tests and analysis by commercial firms.

35.62 and 35.63 The labels on syringes and vial shields should also contain the activity of the radiopharmaceutical.

35.70 An action limit for fixed and removable contamination should be established.

35.75(a) In some cases, specifically for I-131, the exposure rate of 5 mR/hr is too high if the limit is to be 30 mCi total in the patient's body. On a laboratory bench, the exposure rate at one meter from 100 mCi of I-131 is 20-21 mR/hr. Immediately after a patient swallows the dose one exposure rate at one meter from the center of the stomach is approximately 11-16 mR/hr, depending on the tissue mass of the abdominal wall over the stomach. To more accurately measure the residual I-131 in the body with time, a "zero time" measurement should be compared to subsequent measurements. Furthermore, measurements taken at a distance of one meter will change (decrease) with the redistribution of the I-131 in the body. A reading taken at one meter from the stomach one hour after the dose and before any excretion has occurred may be lower than the "zero time" reading, because of redistribution. In addition to the one meter reading it is wise to also make and use measurements at two and four meters distance.

35.80 Rules for mobile nuclear medicine services need to address the container used to transport syringes with regard to absorbent material, labeling and other U.S. Department of Transportation requirements, and emergency transportation instructions in case of accident.

35.92 Decay-in-storage could cause a problem if the licensee is not required to strictly enforce what goes into the waste containers. Also, a survey should be done inside the container as well as at the surface. This section should also include a statement that

the licensee must observe any state or federal rules regarding the hazardous or toxic properties of the material.

35.200 Many of the smaller hospitals do not use generators. This rule would authorize the use of generators whether or not they were needed.

35.205(f) Xenon trap check should be based on times used rather than interval of time. Consideration should be given to complications caused by moisture, etc.

35.315(g) The requirement for a measurement of thyroid burden on personnel administering therapeutic dosages of I-131 needs to specify that bioassay be performed if liquid rather than capsule doses are used. The unique identification of meter used should be recorded along with the other required information.

35.500(c) Lixiscopes should not be included as a general rule for use of sealed sources for diagnosis until the Food and Drug Administration has completed their review.

35.910 and 35.920 Putting training requirements in the rules rather than in regulatory guides is a good addition by making the requirement easier to enforce.

If you have any questions regarding these comments, please contact us.

Yours truly,

David K. Lacker

David K. Lacker, Chief
Bureau of Radiation Control

cc: Donald A. Nussbaumer
Office of State Programs

STATE OF WASHINGTON

DEPARTMENT OF SOCIAL AND HEALTH SERVICES

Olympia, Washington 98504

March 28, 1985

N. Palladino, Ph.D.
Chairman
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Palladino:

On 22 February 1985 we were supplied with a current copy of your staff's proposed revision to 10 CFR 35. We have also received a letter to you dated 14 February 1985 from A. Godwin, Director of the Alabama Agreement State Program, with which, in general, we agree.

We entirely agree with the proposal to incorporate the many diverse requirements now extant in this area into one coherent document. Indeed, we intend to follow that course ourselves during the next revision of our state regulations.

Specific comments on the proposed changes to 10 CFR 35 appear as an attachment to this letter.

In addition, I offer these comments on your accompanying explanatory material and enclosures:

1. Proposed changes seem to relieve licensing staff of some of their current responsibilities and to place these responsibilities with the field inspector. We do not believe that a field inspection is the appropriate place to both review the licensee's current practices and determine that all changes which the licensee may have made since the prior inspection are appropriate. In addition, the current proposal to allow licensees to modify their own programs and facilities may allow a licensee to unknowingly remove or degrade a system essential to radiation safety without detection/correction for months before the next inspection (provided, of course, that the next inspector will notice all these changes and their ramifications).

   This places an unenviable burden on the inspector who will, realistically, need to spend an average of two to three times the amount of time currently spent per inspection. Allowing applicants to "simply certify" that they will follow model procedures will not, in our opinion, ensure the safety of radiation workers and the public.

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2. Although the primary reason for revision of 10 CFR 35 at this time is to incorporate and unify the many diverse regulatory requirements now active in several different forms, the proposal continues to refer to Regulatory Guides to aid the licensee in determining the adequacy of their own changes. If Regulatory Guides (such as 8.20, etc.) are not to be used, then their provisions should be specifically included in 10 CFR 35.

3. Removal of the word "operable" from all references to meters, equipment, etc. seems reasonable. However, we believe that the simple insertion of this word in the regulations, where appropriate, will obviate the need in the future to constantly explain to licensees that meters must, in fact, be operable.

4. Under the proposed "Transition Policy for Specific Licensees", it is stated that the Nuclear Regulatory Commission will for the first time review the credentials of the Qualified Expert and the RSO. This proposal may cause some licensees to delay submitting timely requests for relatively minor amendments because they don't want to bother submitting involved training and experience summaries for the RSO and Qualified Expert at that time.

In summary, we agree with the comments made by the State of Alabama and, while heartily endorsing the concept of consolidation, do not believe licensees should be allowed to modify procedures, equipment, locations of use, etc., without appropriate regulatory review. We thank you for your time, consideration, and this opportunity to comment.

Sincerely,

John A. Beare, M.D., M.P.H.
Director
Division of Health ET-21

cc: A. Godwin, State of Alabama
M. Blazek, State of Oregon
Agreement States Program, NRC

ATTACHMENT

Washington State Comments on Proposed 10 CFR 35 Changes

1) 35.17 does not appear to address use of nuclides not already authorized.

2) 35.31(b)(3) appears to allow non-institutional medical RSO's and Management (frequently the same person) to make changes which affect radiation safety without any regulatory review.

3) 35.36 allows the licensee to change procedures and locations of use without regulatory review. This is not desirable.

4) 35.50(a) requires the use of a dose calibrator by all medical licensees. This will mean that many licensees (General Licensees, also?) will have to purchase a dose calibrator and related equipment, even though they use only pre-calibrated unit dose.

5) 35.51(1) is a requirement for an actual source calibration up to 1 R/hr consistent with ALARA?

6) 35.51(2) should include a provision specifying which two readings on each scale must be calibrated (one-quarter and three-quarter full scale, two or more points separated by at least 50% of full scale, etc.).

7) 35.58 While we are aware that the NRC does not regulate the use of Radium 226, does this section imply that use of the previously referenced 10 microcurie Radium 226 check source will require a line item amendment?

8) 35.59(f)(4) Refers to leak test exemptions for stored sealed sources. Washington State has removed this provision from our regulations.

9) 35.59(i) The calibration data for the survey meter used should also be noted.

10) 35.70(f) Any minimum or maximum surface area?

11) 35.70(g) Any guidance or regulatory parameters for action levels?

12) 35.70(h) Records should also include the meter's calibration date.

13) 35.92(b) Records should also include meter's serial number and calibration date.

14) 35.120 A maximum of 1mr/hr seems most inadequate.

15) 35.204(a) appears to exceed current requirements of microcurie/millicurie by 1.5 times. Why no total Mo/dose limit? (Currently a maximum of 5 microcuries per dose.)

16) 35.205(f) Quarterly may be more appropriate than every six months.

17) 35.220 Again, a maximum of 1mr/hr seems most inadequate.

18) 35.310(a) Should dose rate limits also be referenced?

19) 35.315(d) The requirement that both the RSO and an Authorized User must authorize every patient visit on a case-by-case basis seems unnecessarily stringent.

20) 35.315(e) Is any documentation required?

21) 35.315(f) requires each licensee to know the efficiency of each instrument used for each nuclide surveyed. Any requirement for records of such efficiency determinations and surveys?

22) 35.315(g) This section seems particularly deficient. Techniques, procedures, and equipment must all be adequate and appropriate to yield any meaningful statistical results. If no regulatory review is required, there is no assurance that such equipment and techniques are appropriate. Also, without using Regulatory Guide 8.20, what action levels must a licensee use?

23) 35.320 Again, a maximum of 1mr/hr seems exceptionally low.

24) 35.400 Is there any requirement for the licensee to maintain in legible form a copy of the manufacturer's instructions for each type of source? This section does not address the increasingly prevalent practice of ophthalmic (intraocular) treatment using interstitial I-125 seeds in a Gold matrix.

25) 35.404(a) Should add "and accounted for" to the end of the last sentence.

26) 35.404(b) "Within" one meter, or at one meter? Records should include meter serial number and calibration date.

27) 35.406(a) Any guidance on how to count? (Audioradiograph, physical count, etc.)

28) 35.406(b) and (c) Records should include patient name (not room or patient name). Records should also include the meter serial number used, the date, a diagragm, appropriate dose rates, adjacent area surveys, and initials of the person performing the survey.

29) 35.420 Does this section intend to prohibit the use of ion chambers with a maximum range greater than 1R/hr? Also, what about licensees whose meters apparently meet the range requirement but use GM's and not ion chambers?

30) 35.500 Is the use of other sources, such as Gadolinium, authorized elsewhere, or simply totally precluded?

31) 35.520 This requirement is inconsistent. If diagnostic field sources need to be surveyed with a low range meter, then they shouldn't need to be surveyed with a high range meter (and vice versa).

32) 35.600(a) The word "and" should be changed to "or". As currently written, this requirement could be interpreted to apply to only those units which have both a Cobalt 60 and a Cesium 137 source.

33) 35.610 If safety procedures are not to be reviewed by any regulatory authority, then standards/generic safety procedures should be added here.

34) 35.615(a) Should such doors also normally be closed?

35) 35.620 The requirement for a low range meter here seems totally inappropriate.

36) 35.621(d) Is this a check with an actual radiation source?

37) 35.621(f) Use of alternate survey instruments or personal dosimeters should also explain how such instruments are to be checked at the beginning of each day of use, in addition to calibration/frequency requirements and records retention.

38) 35.632(b) Are full calibration measurements in air or were they with a phantom?

39) 35.632(6) What, specifically, is acceptable accuracy here?

40) 35.632(e) Monthly decay corrections for Cobalt 60 units are acceptable. However, six months or twelve months also seems acceptable for a Cesium 137 unit.

41) 35.633(a) "Once each calendar month" might be changed to "At intervals not to exceed 30 days" to preclude a 59 day interval.

42) 35.633(h) You may wish to add at the end "and demonstrated to be functioning properly".

43) 35.641(2)(i) The phrase "are not likely" does not seem consistent with ALARA.

44) 35.641(c) Should also include meter serial number, manufacturer, and calibration date.

45) 35.900(b)(6) Is Nuclear Medicine Certification adequate/appropriate for use of teletherapy?

46) 35.940(b)(2) The need for inventories should be included here.

47) 35.972 How much "continuing experience" must the individual have had?