



Rec'd 4/1

Bollinger

rec'd 4/15
mlm

PATRICIA L. NORTON
SECRETARY

OFFICE OF AIR QUALITY AND NUCLEAR ENERGY

GREG J. GASPERECZ
ASSISTANT SECRETARY

March 20, 1985

Donald A. Nussbaumer
Assistant Director for
State Agreements Program
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Draft of 10 CFR 35

Dear Mr. Nussbaumer:

After reviewing the latest NRC staff proposal on 10 CFR 35, the Nuclear Energy Division staff offers the following comments for the NRC staff's consideration:

1. Incorporating essential radiation safety requirements now scattered in various regulations, license conditions, regulatory guides and other staff positions into 10 CFR 35 is a concept the Division supports.

2. Some sections of the current draft contain statements that may not ensure adequate protection from radiation or that appear unwarranted. Specific examples and relevant comments follow:

a. Section 35.18: Many licenses list the names of several authorized users of radioactive drugs. The requirement, as stated, would create unnecessary work for both the licensee and the regulatory agency's staff.

b. Section 35.36: This section does not appear to provide a method to assure that the licensee will maintain adequate equipment and procedures to protect health and minimize danger after license issuance, as required by 10 CFR 33 prior to issuance of the license.

8509230727 850906
PDR PR
35 50FR30616 PDR

Mr. Donald A. Nussbaumer
March 20, 1985
Page 2

c. Section 35.51 (b)(2): A licensee could calibrate a survey meter at two close points on the scale and still be in compliance with this section. This could be avoided by adding the words, "widely separated," or by specifying that the two points be "separated by at least 50% of the scale," as has been described in licensing guides or other regulations.

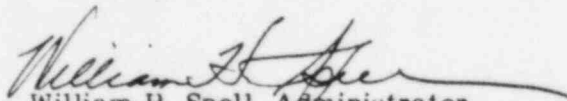
d. Sections 35.315(d) and 35.410: Currently, instructions are given to nursing staff for visitor control in accordance with guidelines similar to those found in NCRP 37. It is thought that such procedures have been adequate in the past, and the need for more restrictive requirements has not been demonstrated.

3. The proposal to codify all regulations and license conditions into a single document appears to be a step in the right direction; however, the Division does not support a procedure that apparently would no longer require the licensee to follow procedures evaluated by the licensing agency as a prerequisite for issuing the license.

4. In the face of budget cuts and the prospect of decreasing revenues available, the Nuclear Energy Division cannot afford to pay additional travel expenses for longer inspections when the same procedure review can be performed at the Division's office. Further, a busy nuclear medicine department would object to an inordinate amount of time being taken to review written procedures during an inspection. Many violations result from time constraints placed on nuclear medicine technologists, and the regulatory agency should not add to the problem. An inspector is not likely to observe the total operation, since all sources of radiation are not used every day. Therefore, emphasis during inspections should be placed on assurance that adherence to established procedures is most likely the rule rather than the exception. This is the most cost-effective way of regulating this segment of the nuclear industry.

Thank you for providing this opportunity to comment on such an important issue. While the Division realizes that this is not a matter of compatibility, uniformity among states and the NRC is a most desirable objective, and if a consensus can be reached, such uniformity is much more likely to result. If clarification of the above comments is desired, please feel free to contact this office.

Sincerely,


William H. Spell, Administrator
Nuclear Energy Division

WHS:SCC/whs



STATE OF NEW MEXICO

ENVIRONMENTAL IMPROVEMENT DIVISION
P.O. Box 968, Santa Fe, New Mexico 87504-0968
(505) 984-0020
STEVEN ASHER, Director *

GOVERNOR

Joseph Goldberg
SECRETARY

Ted Guambana
DEPUTY SECRETARY

JOSEPH F. JOHNSON
DEPUTY SECRETARY

March 23, 1984

Mr. Donald A. Nussbaumer
Assistant Director for
State Agreements Program
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Nussbaumer:

Thank you for your consideration in allowing us to comment on NRC's proposed revision of 10CFR Part 35 and Regulatory Guide 10.8.

The State of New Mexico, after reviewing NRC's proposed regulation changes and implementation of those regulations, believes that the unification of all standards that specifically apply to the human use of byproduct material is needed, but that implementation of greater flexibility under licensure is not a desirable approach to regulation.

In New Mexico, as in most other Agreement States, the turnover in personnel at human use facilities does not allow for continuity in many use procedures, or in many cases, procedures are not implemented due to ignorance on the part of administration or management personnel. We feel that NRC's flexibility implementation would tend to allow this situation to become more prevalent and possibly the norm in human use facilities.

NRC's overriding reason for the flexibility implementation seems to be savings in manpower or man hours spent on licensing endeavors. New Mexico believes that the flexibility implementation will entail an increase of inspection man hours spent on each human use facility because inspectors will be faced with many unknowns at time of inspection. Inspectors will have to familiarize themselves with programs on the spot, review procedures, make recommendations and eventually spend much time on follow-up inspections as well as on interactions with licensing personnel on license amendments. - -

The following specific comments are rendered on the draft Commission Paper.

1. P. 10 "The Public" The premise on exposure seems to contradict the ALARA principle.

8509230537

2. P. 12. "Effect of Selecting Alternative 3" We do not agree with the negligible costs statement and believe that safety at facilities might very well be negatively impacted by the flexible implementation of procedures.
3. P. 13. "Certify" Perhaps the NRC should also certify that such proposed rule making will not have a negative safety impact on small entities.
4. PP. 7-14 "Discussion of Alternatives". It seems that NRC has already decided to implement alternative #2 and the section was written to substantiate that decision. This decision seems to make a request for comments just a perfunctory act.

The following are comments specific to Draft 10 CFR Parts 30, 31, 32, 35 and 40:

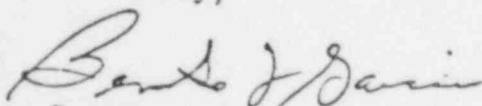
1. P. 1. "Last Sentence". Efficiency as proposed here seems to be equated with a lack of service to licensees; no interaction with licensees does not mean regulation is more "efficient".
2. P.3. "Paragraph 2" The number of treatments should be of no concern to the NRC if treatment is strictly the purview of the physician. This does not seem to be in accord with exposure to the public on P. 10 of the Draft Commission Paper.
3. P. 7. "Paragraph 2" The incompleteness or inadequacy of applications indicates that an applicant is not knowledgeable about human use programs and needs assistance; NRC would eliminate this indicator of a problem by allowing applicants a blanket "I do" statement to all regulatory requirements without review. In essence, NRC is attempting to solve a problem by removing the indicator. (i.e., "If we don't perceive a problem there is no problem").
4. P. 13. "Paragraph 11". This paragraph seems to contradict NRC's flexibility cost containment endeavors.
5. P. 14. "Last Paragraph". These letters and phone calls seem to be replacements for those which would be made during license review.
6. P. 19. "Records Retention". The type of records mentioned should be kept for a minimum of two years, or from the date of the last inspection if more than two years.

Mr. Donald Nussbaumer
March 23, 1984
Page 3

7. P. 27 "Qualified Teletherapy Calibration Expert" needs to be defined as to qualifications and duty requirements.
8. P. 27. "Radiation Safety Officer" needs to be defined in terms of qualifications and duties specifically in diagnostic vs therapy facilities.
9. P.27. "Last Paragraph". The term management should be replaced by the term administration or defined to include administration.
10. P. 32. "Radiation Safety Officer". Special qualification and expertise should be defined.
11. P. 35 "Mobile Service". This statement needs to be clarified. Does this statement mean that an unlicensed person is being allowed to possess and use radioactive material?
12. P. 57 "Last Paragraph". The procedures involving a monthly spot check should be clarified. In some cases monthly spot checks are not feasible and exemptions should be allowed.
13. P. 115 "Last Paragraph". Parts 35.320 and 35.220 should be combined with 35.520.
14. P. 134 "Radiation Safety Officer". Item "b" should be eliminated since qualification could vary so much between different licensed facilities.

Please feel free to contact Benito J. Garica or Eloy Montoya on these comments at (505) 984-0020 Ext. 292.

Sincerely,



Benito J. Garcia
Program Manager
Licensing and Registration Section

BJG/mp

cc: Michael H. Mobley
Chuck Hardin, CRCPD
Tom Buhl, Chief
Radiation Protection Bureau