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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 flexibilty 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.

2. P. 12. "Effect of Selecting Alternative 3" We do not agree with the negligible costs statement and believe that safety at facilites 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 descision. 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 imcompleteness 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 percieve a problem there is no problem").

4. P. 13. "Paragraph ii". 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.

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 or 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
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BJG/mp

cc: Michael H. Mobley
Chuck Hardin, CRCPD
Tom Buhl, Chief
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GEORGIA DEPARTMENT OF HUMAN RESOURCES

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rec'd 4/03/84 mlw

March 23, 1984

Mary Lou Blazek
Radiation Control
State Health Division
P. O. Box 231
Portland, Oregon 97207

Dear Mary Lou:

This letter is concerning NRC's draft documents on their revision of Part 35 dated 02/13/84, 02/08/84 and 02/09/84. Due to the time element I will not comment on the Proposed Revision 2* to Regulatory Guide 10.8 except very briefly in certain areas. I would also like to say that I have always tried to remain open to suggestions and policy changes; however, the document that I just reviewed is such a total reversal of NRC's past policies and concerns for assuring the safe use of byproduct, source and special nuclear material that I was overwhelmed.

To begin with I would like to point out the importance and far reaching effect that we are considering with this proposal:

1) The sample application used as Exhibit 3 with the Proposed Revision 2* to Regulatory Guide 10.8 (also attached to this letter) implies that this form will be the application form for all domestic licensing of byproduct, source and special nuclear material (10CFR30, 40 and 70). I believe that this "streamlining" the licensing process in all areas is the underlying intention of the proponents of this concept, and I believe everyone reviewing these documents should keep this in mind.

2) I also have read throughout this document that the intention was to consolidate all requirements that apply to human use into one document. I have no objections to that idea when you are considering requirements for all such applicants (or regulations) but I do not understand how models or "guidelines" that may or may not be followed can be put into Title 10, Code of Federal Regulations, except as Regulatory Guides.

3) I would also strongly recommend to the Commissioners that if they should accept this proposal, the comment period should at least be extended to 120 days or more due to the potential impact not only on regulators and licensees but also on employees of the licensees and the general public.

More detailed comments are as follows:

Draft Memorandum for William Dircks from John G. Davis:

I cannot speak on behalf of all individuals listed in this memorandum, but to

Draft Memorandum for William Dircks from John G. Davis (Continued)

the knowledge of the task force representing the Agreement States, the Agreement States did not help prepare this proposal. We were "lucky" to see the proposals after they were prepared and before publication as proposed rules.

Draft Commission Paper

1) The comparison used on page 2 between NRC's general license for human use (very small microcurie quantities) to the use of everything from diagnostic to therapeutic quantities is like comparing a city or county government to the federal bureaucracy. Another such absurd comparison is located on page 5 where a non-institutional facility (private physician's office) is "compared to technical specifications that apply to reactor licensees." This comparison was used when stating "licensees would be free to make changes in procedural detail to meet changed operating needs." How does the technical expertise, operating needs or anything else at a reactor facility compare to a one-physician, private-practice office?

2) Another rationale for streamlining came on page 5 and elsewhere throughout the document that "to allow each licensee to make prompt use of new safety methods and to adjust procedures to meet new needs caused by changes in need for patient care services or patient load, licensees will be free to modify their procedures without NRC review or approval...." The procedures we have submitted with the application are radiation safety procedures and not cookbook how-to-do-everything procedures as implied. I have never been aware that submission of these procedures jeopardized patient care. If the NRC or Agreement State were aware of this situation, there are immediate ways of remedying the problem in this unusual case. Licensees are not cited for using an improved, safer method of doing something. The problem with the vast majority of changes in procedures is simple negligence or relaxation of the procedures, and therefore we have a number of violations in this area.

3) Also, on page 5 of the Draft Commission Paper it states that "A licensee will be cited for failure to meet the requirements of the regulations or license conditions..., failure to have the written procedures required by the regulations, failure to follow those procedures, failure to have the records required by the regulations, or failure to follow technically valid procedures." I feel sorry for the inspector who tries to determine what the procedures are(when they can change any day), whether they are adequate, and whether they are being followed. I think it is unreal to ask the inspectors to try to do this, and in fact, it will probably not be done.

4) On page 7, it states that the staff is not aware of anyone who would recommend retaining the current Part 35 over the proposed revision. Georgia would prefer retaining the current version over the proposal,especially over Alternate 2.

5) "Effect of Selecting Alternate 1" states that it "does not provide any greater degree of safety than the other alternative." I disagree for the following reasons:

   a) Review prior to a program starting up allows for problems to be solved prior to the occurrence and prior to citations and fines. Anyone knowledgeable in compliance work realizes that it is easier to prevent something than to

5) a) (Continued)

solve the problem once it has occurred. Had we been aware that Luminous Processes was using a septic tank rather then sewer system (as we had been told) and had been aware of some of their old practices, Georgia may never have needed to file for Super Fund money.

b) Filing an application is an educational process for the licensee and for the licensor. I was told today by a health physicist that he helps licensee's complete application forms but always takes the time to educate the applicant before it's mailed in, because he feels it's a vital part of the process.

c) The procedures in the regulations as guidelines (?) may be outdated, and not the best procedures to follow; however, it is going to be easier for a licensee to say he will follow those guidelines than to draw up new ones. It would also be easier to follow the regulation "guidelines" than to bother having your hospital committee review and approve new ones even if they were better than those proposed by the NRC.

d) This argument also says that it is difficult to maintain standardization, but I'm not sure why you want standardization on "guidelines" or how you standardize programs whose radiation safety procedures, in-house locations and equipment can change anytime.

6) Alternative 2 (or the Proposed Revision Part 35 as presented) allows the licensee to be free to modify facilities and procedures or replace equipment with the approval of the Radiation Safety Officer and management (private-practice medical) or the Radiation Safety Officer and the Radiation Safety Committee. My concerns are as follows:

a) Why review these things to begin with if they can change anyday? I have got to think the proponents of Alternate 2 are not complying with the directive of the Commission when "The Commission has decided to continue the pre-licensing review of applicants' operating procedures ..."

b) In a private-practice medical office, the authorized user, the Radiation Safety Officer and the management will all be the same. The way this is written is a facade. The licensee could change the licensed program however he wanted and whenever he wanted.

c) In the institutional programs, the Radiation Safety Committee is required to consist of at least three individuals and must include an authorized user, the Radiation Safety Officer, a representative of the nursing service, if there is one, and a representative of management. In most institutions the Radiation Safety Officer is also an authorized user and may represent both on the committee since there only needs to be three members. The representatives

6) c) (Continued)

of the nursing service and management will not have expertise in radiation safety. Thus, you may have one person who is the authorized user on the license making these decisions. Many physicians will tell you (especially when going through the licensing process and first inspection) that although they had some on-hand or classroom radiation safety training during their residency they did not retain what they were taught since it was not essential to the medical applications such as diagnosis and treament of diseases, and they were not required to use it at medical school since the radiation safety office or health physicist took care of those problems. They are usually in shock when they find out that they need radiation safety procedures for themselves and their technologists.

7) The argument has been used concerning putting all critical safety elements for human use in Part 35 so the NRC would not continue to review detailed applications. Some of these "critical safety elements" are guidelines. The detailed application is like an architect's plans for a house which demonstrates compliance with building codes. I certainly wouldn't want all plans for houses to be "standardized" and put into the building codes!

8) The argument was also made that the proposal would be less costly for both the NRC and the licensee. If a licensee was fined for all violations and if they were inspected thoroughly or more often, I suspect that the proposal would not be less costly for the licensee. If the NRC inspector does a thorough inspection, it will mean more inspection hours. If he or she has to review procedures and believes they are not compatible with the ALARA concept, will he be able to cite the licensee and fine the licensee? If judgemental decision are made, will there be more appeals to the citations and will the inspector be supported? If not, you will have low morale among inspectors, and in the long run may cost the NRC in money and time.

It is difficult for me to believe that anyone who is truly concerned with radiation safety would push so hard for this concept.

Sincerely,

Carol Connell 404 894 5795

Carol Connell, Chief
Radioactive Materials Unit
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CC/ck