VICTOR ATIYEH
GOVERNOR

*Department of Human Resources*
HEALTH DIVISION
1400 S.W. 5th AVENUE, PORTLAND, OREGON 97201 PHONE 229-5797

1 03 85
mlm

December 27, 1984

'84 DEC 31 P2:59

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

Mr. Nussbaumer:

I have briefly reviewed the latest draft revision of the proposed changes to Part 35. My major concerns remain unchanged from previous drafts and previous comments. I object to the description of the Agreement States' non-concurrence on page 3 of the cover document to the Commissioners. The word "minor" in the following statements allowsa misconception of the true concerns.

> "The latter three believe that many licensees do not have the expertise needed to make an adequate safety review of minor [emphasis added] changes in their radiation safety programs..."

Page 2 of the cover document:

> "...in order to allow each licensee to make changes for improved patient care, safety, or reduced cost, licensees will be free to make minor [emphasis added] changes without NRC review or approval..."

Page 5 of the cover document:

> "At issue here is whether or not a regulatory agency must approve minor [emphasis added] changes in a licensee's day-to-day radiation safety program."

Page 2, Enclosure 10, Discussion of Alternative 2:

> "Licensure connotes that the key users are competent to make minor [emphasis added] radiation safety program changes..."

Page 3, Enclosure 10, Discussion of Alternative 2:

> "Independent review of minor [emphasis added] changes by a governmental agency will not provide a significant public health and safety benefit but is expensive."

I have been unable to find definitions of what "minor" and "major" changes are and in fact find no mention of "degree" in the overview of the proposed revision.

Page 6, Enclosure 1:

> "...allow medical licensees to modify their radiation safety procedures,..."

Page 8, Enclosure 1:

> "...licensees will be free to modify their procedures without NRC review or approval."

It appears that the licensees may substantially change procedures (i.e., survey frequencies, both type and frequency of bioassays, etc.) to <u>any</u> "degree" without prior review and approval. This is justified in this draft by calling it a "minor" change which will be corrected <u>after</u> the next regularly scheduled compliance inspection, perhaps five years hence.

Implying that the Agreement States object to "minor" changes made by qualified, responsible,active Radiation Safety Committees is inaccurate and unacceptable. Allowing potential health and safety related changes to be made after review by a disinterested,peripatetic Radiation Safety Committee also continues to be unacceptable.

In addition, it is inappropriate to compare medical licensees to operating power reactors. Again, it appears that only large medical licensees are being considered for this comparison; certainly, one cannot compare the multitude of <u>small</u> nuclear medicine facilities with power reactors.

It is unclear how NRC staff determined that no significant changes in Agreement States staff resources would be necessary to implement this proposal. Certainly the Agreement States Task Force members have endeavored to clearly state that this most assuredly will be the case. Hence, potentially significant cost for the public.

Should you have any questions or if I may be of further assistance, please contact me at 503-229-5797.

Sincerely,

Mary L. Blazek

Mary L. Blazek
Radiation Specialist
Radiation Control Section

MLB:mas

cc: C. Connell, Georgia
P. Eastvold, Illinois
C. Hardin, CRCPD, Kentucky
N. McElroy, NRC, Washington DC
M. Mobley, Tennessee
J. Ward, California
K. Whatley, Alabama

State of Alabama

DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

IRA L. MYERS, M.D.
STATE HEALTH OFFICER

February 13, 1985

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sir:

In response to the latest revision of 10CFR35, as supplied by the Agreement States Program on January 14, 1985, the following comments are offered:

1. The concept of incorporating "essential radiation safety requirements that are now contained in regulations, license conditions, regulatory guides, and staff positions" into the revised 10CFR35 is fully supported.

2. Numerous sections of the proposed revision to 10CFR35 contain statements that are questionable with respect to radiation protection. Several are listed below:

   a. 35.18. Notification is certainly appropriate for a "one or two physician license." However, many licenses contain the names of numerous authorized users. Such a requirement, as stated, appears to create unnecessary work for both the licensee and NRC staff.

   b. 35.36. "A licensee may change the radiation safety procedures and equipment ..... and store licensed material in areas of use not identified in the application ...."

      10CFR33 requires NRC to determine that "the applicants proposed equipment and facilities are adequate to protect health and minimize danger to life and property" prior to issuing a license. This should also imply that equipment and facilities remain adequate. The proposed 35.36 does not appear to provide reasonable assurance that 10CFR33 will be complied with.

~~8504170205~~

6pp.

c. 35.51(b)(2). A licensee could calibrate on a 0-1 R/hr. survey meter scale two points, 2 mR/hr and 3 mR/hr, and be in compliance with this section. If the intent of the change is to make clear the requirements, one should not have to seek further guidance in documents such as revised Reg. Guide 10.8. Clarity could be added by adding the words "separated by at least 50 percent on each scale" which is "standard," understandable wording. Comments on this section have been made on numerous drafts of Part 35.

d. 35.59(g) requires records of inventory to be maintained for five years. Since other records are maintained for only two years, why have one different?

e. 35.62. Many radiopharmaceuticals are drawn up and administered on-the-spot to patients. Does this require all syringes to be labeled? The requirement is understood for many facilities where syringes are prepared in advance. The majority of users do not fit in this category. The intent of this requirement is supported; however, it appears impracticable for all cases.

f. 35.59(i) (and other sections). The statement, "the measured exposure rate at several points in each area expressed in millirem per hour," appears in several sections (or a statement similar to it) (35.80(f), 35.404(b)). Requirements for survey meters (35.120, 35.220, 35.320, 35.420, 35.520, 35.620, etc.) require that survey meters be available which have scale deflections expressed in roentgens or milliroentgens. Should not units of exposure and dose be consistent with units required on survey meters? Even if qualifying factors for conversion are all unity, the regulations should be consistent.

g. In 35.220 the word roentgen is spelled "roentgen" and in 35.320 it is spelled "Roentgen" (See 35.420 and 35.520 also). Regulations should be consistent.

h. 35.315(d) and 35.~~420~~ 415. It is not understood why the authorized user and radiation safety officer must approve "on a case-by-case basis" visiting privileges for all persons under 18 years of age. Most family members visit at night due to work or school. It is unlikely that both the user and safety officer are on site to approve visitors.

Previously, standing orders were given to nursing staff for visitor control. To my knowledge such procedures were adequate. The need for both approvals is not understood. Why instructions could not be given to nursing staff is not understood.

i. 35.620 permits a licensee to use a survey meter which has a scale of 1 milliroentgen per hour to be used for entering a teletherapy room to monitor for any malfunction of the source exposure mechanism (or partially exposed source). The section, does not require that the survey meter have any scale higher than 1 milliroentgen per hour, as currently worded. Such an instrument is inappropriate and inacceptable for performing surveys required by 36.621(f). This item has been commented on in previous correspondence with NRC staff. A survey meter having a full scale deflection of 1 roentgen per hour is required for users of bone mineral analyzers which contain millicurie quantities of iodine 125 -- yet not required for thousands of curies of cobalt 60?

j. 35.641(a)(1) requires that surveys be made with the collimators set for a normal treatment field. This is supported. However, many teletherapy units can no longer meet the standard if the collimators are open when the survey is made. There has been no standard for measuring the exposure rate at one meter with respect to the collimators being opened or closed. Field experience indicates that surveys have been (if not usually) made with the shutters closed to achieve compliance. It is possible that this requirement might necessitate modification to many teletherapy units or NRC's writing exceptions to the regulations.

3. Several sentences describing current licensing practices appear in enclosure 1 of the packet as follow:

a. Page 5, 3rd paragraph. "Application review practice must be conservative ..... deficiency letters are costly to NRC and the applicant ..... etc."

b. Page 6, 3rd paragraph. "Therefore, it was necessary to regulate by reviewing each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment."

NRC staff has used statements like the above to criticize the current licensing procedures. Yet, the most recent draft version contains the following statement:

> Page 8, Paragraph 2 of enclosure 1. "After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter .... and request clarification."

Comment: If NRC staff does not plan to regulate by reviewing each individual safety program why is it requiring that procedures be submitted for review? Why will NRC staff continue to issue deficiency letters until procedures are adequate? The NRC staff had used statements that generation of procedures were costly for applicants. The proposed method appears not only costly to applicants but totally unnecessary since the applicant will not be required to follow those procedures.

4. It is important for the Commission to understand that NRC staff is presenting two proposals to the Commission, not just one.

   The first proposal is to codify all regulations in a single document -- the revised 10CFR35. Again this is supported.

   The second proposal is to continue to review procedures, equipment, etc., but to no longer require the licensee to follow those procedures. This is not supported.

   The staff paper appears to say that "you can't have one without the other." It is recommended that the Commission adopt revisions to Part 35, when corrected, and reject the change in licensing procedure. There is a choice.

5. The following comments are directed to NRC staff response as stated in enclosure 8, "Summary of Unresolved Comments."

   a. A statement was made that the relaxation in licensing is unwarrented in light of NRC inspection frequency.

It is recognized that a license review cannot be substituted for an inspection. However, those of us who work in health prevention are aware of the value of providing means to reasonably assure that problems are not likely to occur. The current licensing policy provides that reasonable assurance. The proposed method does not. Could not the fact that procedures are tied to licenses be "just a little bit" responsible for the good record in radiation safety in nuclear medicine?

b. A comment was made regarding continuing to require applicants to get prior approval for changes that might decrease their program effectiveness (radiation safety).

NRC staff response was that agency resources could be better spent on other problems.

If the purpose of this revision is to decrease staff work in nuclear medicine, the staff has taken much effort and resources over the past several years to camouflage that purpose.

NRC staff should take heed of its own words to write in simple terms so anyone could understand.

c. A comment was made about an inspector under pressing time constraints in the field having to review procedures and program changes.

NRC staff response was that watching what the worker does is more important than reading what the worker is supposed to do.

There is great wisdom to that statement. However, can the NRC afford the cost of having staff spend all day in a nuclear medicine department? Will a licensee be required to conduct "typical operations" for the inspector to view while he is there?

A busy nuclear medicine department is no place to review written procedures for adequacy. An inspector and nuclear medicine staff will be under severe time restraints. They already are under the current system.

During any inspection the inspector is likely to see only a small part of the total operations. Implant sources aren't prepared every day, sources aren't leak tested every day, surveys aren't made every day, instruments are not calibrated each day, radiopharmaceuticals are not received each day, etc. As on any inspection a lot will remain unseen and not reviewed and may(?) be caught on the next inspection, perhaps years away.

Please accept these comments as being offered in a constructive manner. Although NRC staff does not concur with many of the comments, I feel that they are valid and worth consideration prior to adoption of the changes.

Thank you,

Kirksey E. Whatley

Kirksey E. Whatley, Director
Division of Radioactive Material
Licensing
Bureau of Radiological Health
Environmental & Facility Standards
Administration

KEW:mpw

State of Alabama

DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

IRA L. MYERS, M.D.
STATE HEALTH OFFICER

February 14, 1985



N. Palladino, Ph.D.
Chairman
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Re: Proposed 10 CFR 35

Dear Chairman Palladino:

On January 14, 1985 we were supplied a copy of the current staff proposal. After reviewing this we would continue to offer the following comments, most of which were supplied on the earlier staff proposal.

1. The concept of incorporating "essential radiation safety requirements that are now contained in regulations, license conditions, regulatory guides, and staff positions" into the revised 10CFR35 is fully supported.

2. Numerous sections of the proposed revision to 10CFR35 contain statements that are questionable with respect to radiation protection. Several are listed below:

   a. 35.18. Notification is certainly appropriate for a "one or two physician license." However, many licenses contain the names of numerous authorized users. Such a requirement, as stated, appears to create unnecessary work for both the licensee and NRC staff.

   b. 35.36. "A licensee may change the radiation safety procedures and equipment ..... and store licensed material in areas of use not identified in the application ...."

      10CFR33 requires NRC to determine that "the applicants proposed equipment and facilities are adequate to protect health and minimize danger to life and property" prior to issuing a license. This should also imply that equipment and facilities remain adequate. The proposed 35.36 does not appear to provide reasonable assurance that 10CFR33 will be complied with.

c. 35.51(b)(2). A licensee could calibrate on a 0-1 R/hr. survey meter scale two points, 2 mR/hr and 3 mR/hr, and be in compliance with this section. If the intent of the change is to make clear the requirements, one should not have to seek further guidance in documents such as revised Reg. Guide 10.8. Clarity could be added by adding the words "separated by at least 50 percent on each scale" which is "standard," understandable wording. Comments on this section have been made on numerous drafts of Part 35.

d. 35.59(g) requires records of inventory to be maintained for five years. Since other records are maintained for only two years, why have one different?

e. 35.62 Many radiopharmaceuticals are drawn up and administered on-the-spot to patients. Does this require all syringes to be labeled? The requirement is understood for many facilities where syringes are prepared in advance. The majority of users do not fit in this category. The intent of this requirement is supported; however, it appears impracticable for all cases.

f. 35.59(i) (and other sections). The statement, "the measured exposure rate at several points in each area expressed in millirem per hour," appears in several sections (or a statement similar to it) (35.80(f), 35.404(b)). Requirements for survey meters (35.120, 35.220, 35.320, 35.420, 35.520, 35.620, etc.) require that survey meters be available which have scale deflections expressed in roentgens or milliroentgens. Should not units of exposure and dose be consistent with units required on survey meters? Even if qualifying factors for conversion are all unity, the regulations should be consistent.

g. In 35.220 the word roentgen is spelled "roentgen" and in 35.320 it is spelled "Roentgen" (See 35.420 and 35.520 also). Regulations should be consistent.

h. 35.315(d) and 35.410. It is not understood why the authorized user and radiation safety officer must approve "on a case-by-case basis" visiting privileges for all persons under 18 years of age. Most family members visit at night due to work or school. It is unlikely that both the user and safety officer are on site to approve visitors.

Previously, standing orders were given to nursing staff for visitor control. To my knowledge such procedures were adequate. The need for both approvals is not understood. Why instructions could not be given to nursing staff is not understood.

i. 35.620 permits a licensee to use a survey meter which has a scale of 1 milliroentgen per hour to be used for entering a teletherapy room to monitor for any malfunction of the source exposure mechanism (or partially exposed source). The section, does not require that the survey meter have any scale higher than 1 milliroentgen per hour, as currently worded. Such an instrument is inappropriate and inacceptable for performing surveys required by 36.621(f). This item has been commented on in previous correspondence with NRC staff. A survey meter having a full scale deflection of 1 roentgen per hour is required for users of bone mineral analyzers which contain millicurie quantities of iodine 125 -- yet not required for thousands of curies of cobalt 60?

j. 35.641(a)(1) requires that surveys be made with the collimators set for a normal treatment field. This is supported. However, many teletherapy units can no longer meet the standard if the collimators are open when the survey is made. There has been no standard for measuring the exposure rate at one meter with respect to the collimators being opened or closed. Field experience indicates that surveys have been (if not usually) made with the shutters closed to achieve compliance. It is possible that this requirement might necessitate modification to many teletherapy units or NRC's writing exceptions to the regulations.

3. It is important for the Commission to understand that NRC staff is presenting two proposals to the Commission, not just one.

The first proposal is to codify all regulations in a single document -- the revised 10CFR35. Again this is supported.

The second proposal is to continue to review procedures, equipment, etc., but to no longer require the licensee to follow those procedures. This is not supported.

The staff paper appears to say that "you can't have one without the other." It is recommended that the Commission adopt revisions to Part 35, when corrected, and reject the change in licensing procedure. There is a choice.

4. A comment was made about an inspector under pressing time constraints in the field having to review procedures and program changes.

NRC staff response was that watching what the worker does is more important than reading what the worker is supposed to do.

There is great wisdom to that statement. However, can the NRC afford the cost of having staff spend all day in a nuclear medicine department? Will a licensee be required to conduct "typical operations" for the inspector to view while he is there?

A busy nuclear medicine department is no place to review written procedures for adequacy. An inspector and nuclear medicine staff will be under severe time restraints. They already are under the current system.

During any inspection the inspector is likely to see only a small part of the total operations. Implant sources aren't prepared every day, sources aren't leak tested every day, surveys aren't made every day, instruments are not calibrated each day, radiopharmaceuticals are not received each day, etc. As on any inspection a lot will remain unseen and not reviewed and may(?) be caught on the next inspection, perhaps years away.

Thank you for your time and consideration. Many of the Agreement States have concerns regarding the proposed licensing procedures which are not shared by the U.S. NRC staff. We feel our position has validity and we appreciate your consideration.

Sincerely,

Aubrey V. Godwin, Director
Bureau of Radiological Health
Environmental & Facility Standards
Administration

AVG:psc

cc: Agreement States

2/19/85

State of Alabama

# DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

IRA L. MYERS, M.D.
STATE HEALTH OFFICER

February 14, 1985

N. Palladino, Ph.D.
Chairman
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Re: Proposed 10 CFR 35

Dear Chairman Palladino:

On January 14, 1985 we were supplied a copy of the current staff proposal. After reviewing this we would continue to offer the following comments, most of which were supplied on the earlier staff proposal.

1. The concept of incorporating "essential radiation safety requirements that are now contained in regulations, license conditions, regulatory guides, and staff positions" into the revised 10CFR35 is fully supported.

2. Numerous sections of the proposed revision to 10CFR35 contain statements that are questionable with respect to radiation protection. Several are listed below:

   a. 35.18. Notification is certainly appropriate for a "one or two physician license." However, many licenses contain the names of numerous authorized users. Such a requirement, as stated, appears to create unnecessary work for both the licensee and NRC staff.

   b. 35.36. "A licensee may change the radiation safety procedures and equipment ..... and store licensed material in areas of use not identified in the application ...."

      10CFR33 requires NRC to determine that "the applicants proposed equipment and facilities are adequate to protect health and minimize danger to life and property" prior to issuing a license. This should also imply that equipment and facilities remain adequate. The proposed 35.36 does not appear to provide reasonable assurance that 10CFR33 will be complied with.

c. 35.51(b)(2). A licensee could calibrate on a 0-1 R/hr. survey meter scale two points, 2 mR/hr and 3 mR/hr, and be in compliance with this section. If the intent of the change is to make clear the requirements, one should not have to seek further guidance in documents such as revised Reg. Guide 10.8. Clarity could be added by adding the words "separated by at least 50 percent on each scale" which is "standard," understandable wording. Comments on this section have been made on numerous drafts of Part 35.

d. 35.59(g) requires records of inventory to be maintained for five years. Since other records are maintained for only two years, why have one different?

e. 35.62 Many radiopharmaceuticals are drawn up and administered on-the-spot to patients. Does this require all syringes to be labeled? The requirement is understood for many facilities where syringes are prepared in advance. The majority of users do not fit in this category. The intent of this requirement is supported; however, it appears impracticable for all cases.

f. 35.59(i) (and other sections). The statement, "the measured exposure rate at several points in each area expressed in millirem per hour," appears in several sections (or a statement similar to it) (35.80(f), 35.404(b)). Requirements for survey meters (35.120, 35.220, 35.320, 35.420, 35.520, 35.620, etc.) require that survey meters be available which have scale deflections expressed in roentgens or milliroentgens. Should not units of exposure and dose be consistent with units required on survey meters? Even if qualifying factors for conversion are all unity, the regulations should be consistent.

g. In 35.220 the word roentgen is spelled "roentgen" and in 35.320 it is spelled "Roentgen" (See 35.420 and 35.520 also). Regulations should be consistent.

h. 35.315(d) and 35.410. It is not understood why the authorized user and radiation safety officer must approve "on a case-by-case basis" visiting privileges for all persons under 18 years of age. Most family members visit at night due to work or school. It is unlikely that both the user and safety officer are on site to approve visitors.

Previously, standing orders were given to nursing staff for visitor control. To my knowledge such procedures were adequate. The need for both approvals is not understood. Why instructions could not be given to nursing staff is not understood.

i. 35.620 permits a licensee to use a survey meter which has a scale of 1 milliroentgen per hour to be used for entering a teletherapy room to monitor for any malfunction of the source exposure mechanism (or partially exposed source). The section, does not require that the survey meter have any scale higher than 1 milliroentgen per hour, as currently worded. Such an instrument is inappropriate and inacceptable for performing surveys required by 36.621(f). This item has been commented on in previous correspondence with NRC staff. A survey meter having a full scale deflection of 1 roentgen per hour is required for users of bone mineral analyzers which contain millicurie quantities of iodine 125 -- yet not required for thousands of curies of cobalt 60?

j. 35.641(a)(1) requires that surveys be made with the collimators set for a normal treatment field. This is supported. However, many teletherapy units can no longer meet the standard if the collimators are open when the survey is made. There has been no standard for measuring the exposure rate at one meter with respect to the collimators being opened or closed. Field experience indicates that surveys have been (if not usually) made with the shutters closed to achieve compliance. It is possible that this requirement might necessitate modification to many teletherapy units or NRC's writing exceptions to the regulations.

3. It is important for the Commission to understand that NRC staff is presenting two proposals to the Commission, not just one.

The first proposal is to codify all regulations in a single document -- the revised 10CFR35. Again this is supported.

The second proposal is to continue to review procedures, equipment, etc., but to no longer require the licensee to follow those procedures. This is not supported.

The staff paper appears to say that "you can't have one without the other." It is recommended that the Commission adopt revisions to Part 35, when corrected, and reject the change in licensing procedure. There is a choice.

4. A comment was made about an inspector under pressing time constraints in the field having to review procedures and program changes.

NRC staff response was that watching what the worker does is more important than reading what the worker is supposed to do.

There is great wisdom to that statement.' However, can the NRC afford the cost of having staff spend all day in a nuclear medicine department? Will a licensee be required to conduct "typical operations" for the inspector to view while he is there?

A busy nuclear medicine department is no place to review written procedures for adequacy. An inspector and nuclear medicine staff will be under severe time restraints. They already are under the current system.

During any inspection the inspector is likely to see only a small part of the total operations. Implant sources aren't prepared every day, sources aren't leak tested every day, surveys aren't made every day, instruments are not calibrated each day, radiopharmaceuticals are not received each day, etc. As on any inspection a lot will remain unseen and not reviewed and may(?) be caught on the next inspection, perhaps years away.

Thank you for your time and consideration. Many of the Agreement States have concerns regarding the proposed licensing procedures which are not shared by the U.S. NRC staff. We feel our position has validity and we appreciate your consideration.

Sincerely,

Aubrey V. Godwin, Director
Bureau of Radiological Health
Environmental & Facility Standards
Administration

AVG:psc

cc: Agreement States