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March 23, 1984

Norman McElroy
Materials Licensing Branch
Mail Stop SS 396
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Mr. McElroy:

I have enclosed comments prepared by Kirksey Whatley and myself on the February 8, 1984, version of 10 CFR Part 35. Unfortunately, time did not permit consolidation of the comments into one document; however, the fact that many of the comments are repetitive in nature may reinforce some of our major concerns.

Please note objections made both by Mr. Whatley and myself regarding the erroneous and misleading statement "....individuals from....two Agreement States helped prepare this proposal." Prior to January 1984 and your contacts with us, no effort was made to inform us of actions under consideration other than an occasional draft change. This can hardly be considered active participation in the development of Part 35 changes.

I have contacted the members of the CRCPD Ad Hoc Committee on Part 35 and several Agreement States program directors regarding the February 8, 1984, draft. Few if any reservations are held for Alternative 3 by individuals with whom I have spoken; however, it is felt that the resulting impact of Alternative 2 is substantially the same as the original version, which the Commission instructed the staff to abandon.

In conclusion, allowing licensees to capriciously change day-to-day procedures without review by an independent agent is not seen as a viable alternative to the current Part 35 and licensing branch policies.

Should you have any questions regarding these comments, please contact me.

Sincerely,

Mary L. Blazek

Mary L. Blazek
Radiation Specialist
Radiation Control Section

MLB:mas
Enclosures

cc: Lloyd Bolling
Carol Connell
Paul Eastvold
Chuck Hardin
Mike Mobley
Bill Spell
Kirk Whatley

General Comments on 10 CFR 35 Proposed Revision

Submitted by Mary L. Blazek
Agreement States Task Force Member

1. Davis to Dircks memo: The statement in this memo that "two Agreement States helped prepare this proposal" is in error and should be deleted. This statement could more correctly be added as a footnote under the two paragraphs the Agreement States were asked to provide.

2. A. Draft Commission Paper, page 5(3): "....licensees will be free to modify their procedures without NRC review or approval as long as they meet the requirements of the regulations. ....A licensee will be cited for....failure to follow technically valid procedures."

   B. NRC Order dtd 3/30/81 Docket File 030-14826: "....inspections are essentially audits of the licensee's activities, not complete reviews of every aspect of the licensee's operations....inspectors do not ordinarily examine every facet of a licensee's activities."

   Considering the statement in B. above, it appears that a licensee could potentially operate a radioactive materials program for years (considering current NRC inspection frequency of 2-5 years for nuclear medicine) using technically invalid procedures. In addition to the cost of extensive training for field inspectors, the probability of added cost to licensees (and the NRC) due to increased inspection time, fines due to inadequate procedures and the cost of shutdown due to following inadequate procedures should be considered.

3. Effect of Alternative 2 on Agreement States: This alternative, if adopted, would doubtless result in fewer deficient applications in Agreement States as well as NRC states. However, the increased cost to the states and the licensees both financially and in FTE hours for the type of extensive inspections necessary to determine compliance would be unacceptable in many states.

   Procedural modifications capriciously made by one individual acting as radiation safety officer/authorized user/management, with no review by an independent agent, state budgetary limitations requiring lengthy inspection frequencies and the potential for increased worker dose due to the aforementioned, it would be difficult, if not impossible, for many states to justify, accept or implement this alternative.

4. Discussion of Alternative 3: Savings in amendment fees under Alternative 2 are described as insignificant and yet, "the effect of selecting Alternative 3" is described as being costly to both NRC and licensees. From these statements, it is difficult to understand why NRC has chosen to recommend Alternative 2 when there is no disadvantage to Alternative 3. In addition, it appears that the NRC Regionalization should assist in prompt review and approval of safety related license modifications. The review and approval requirement rarely prohibits prompt adoption of modifications in Agreement States.

5. Enclosure 1

   A. Clarification Number 8 Operable: An intermittent mechanical malfunction might make a hood or survey meter inoperable, hardly "an assemblage of metal or plastic that once served a useful purpose."

      The word operable remains "conspicuous in its absence from the proposed regulation"; particularly, when the requirement to remove or obliterate radiation labels is found in 20.203(f)(4) and is included in Part 35 "for completeness."

   B. Records Retention: Since record retention between inspections "would be unreasonable," it will be impossible to determine long-term compliance (at the present inspection frequency) with the licensees own procedures on any ongoing basis.

6. Enclosure 1 - Discussion of Proposed Regulations: It is assumed that the cost of physically changing all in vitro general licenses to specific licenses is insignificant.

7. Enclosure 1 - 35.17 License Amendments: "Except for teletherapy, moving from one room to another within a building would not constitute a change in location of use."

   It appears that since an amendment is no longer necessary for moving a nuclear medicine department from one room to another within a building, NRC is no longer concerned with ventilation rates for xenon users. Certainly, the potential for exposures over a five-year period (inspection frequency) from inadequate ventilation rates and/or recirculated air should be a point of concern.

8. Enclosure 1 - 35.34 Provisional Authorized User: If a provisional authorized user does perform procedures for which he has not been authorized, either by misunderstanding or intent, deleting the 60-day time limit would allow the unauthorized use to go undetected by the regulatory authority for as much as five years. Clearly, this could adversely affect public health and safety during the time that a physician is without benefit of a preceptor.

9. A. Enclosure 1 - 35.75 Release of Patients Containing Radiopharmaceuticals: "The 6 mR/hr at one meter limit is based on the exposure rate from 30 mCi of iodine-131, the most commonly used therapeutic radiopharmaceutical."

   B. Enclosure 8 - 35.75 Release of Radioactive Patients: "30 mCi in patient can't be measured." 35.75 would allow either.

   It is assumed that the statement B. above means that 30 mCi can't be physically measured except as exposure rate as described in A.

10. Proposed Revision 2* to Regulatory Guide 10.8, page 69, 7(d) Accuracy: "If the average value does not agree, within 5%, with the certified value of the reference source, the calibrator will be repaired or adjusted."

    Enclosure 1 - 35.50 Check of Dose Calibrators: "(d) The licensee shall....repair or replace the dose calibrator if the accuracy error exceeds 10 percent."

    Clarify which of these requirements must be met by licensees.

11. Enclosure 1 - 35.220 Possession of Survey Instruments: "....full scale deflection of 1 milliroentgen per hour....and....high level....full scale deflection of 1 roentgen per hour."

    This statement suggests that instruments are to be calibrated in mR/hr. Since 35.70 requires detectability of 200 dpm for wipe samples, if a licensee chose to use a survey instrument for this analysis, what guidance will be given in order to convert mR/hr to dpm?

12. A. Enclosure 1 - 35.315 Safety Precautions (f): "....The room must not be reassigned until removable contamination is less than 200 disintegrations per 100 square centimeters each second" (emphasis added).

    B. Appendix R 13(c): "Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2."

    It is assumed that "second" in paragraph A is a typographical error. If this is a correct statement, justification for this gross increase should be provided!

13. Enclosure 4 - page 3, Consequences of the Proposed Action on Agreement States: It is projected that many Agreement States could anticipate an increase in safety related items of noncompliance due to procedural changes made by small and/or remote licensees without review by an independent agent, as proposed in Alternative 2. However, the revision to Part 35, if adopted as Alternative 3, could achieve the goal of removing confusion in industry while retaining what many believe to be necessary, established procedures for radiation safety. It is anticipated that most Agreement States would favor retaining the current system if the alternative is the proposed method of implementation.

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Comments on the February 8, 1984, Draft
10 CFR 35

1. The "new" method of medical licensing being proposed by NRC appears on face to be an effort to circumvent the directions of the Commission that procedures be reviewed prior to licensing. The NRC does propose to review a licensee's procedures prior to licensing; however, any licensee may change those procedures at any time without review. In fact, such procedures could be changed by the applicant prior to completion of review by NRC Staff.

   Under the new NRC proposal the real purpose of reviewing procedures submitted by applicants is questioned. The purpose such a submission and review serves is questioned.

   The Commission instructed the Staff of NRC to "continue the pre-licensing review of applicants' operating procedures". It appears that the Commission meant more than a review for the sake of reviewing. If all that is required by NRC is the submission of a set of procedures which meet NRC criteria, then it is predicted that a "standard set of procedures" will be developed and submitted by most applicants. This would be acceptable provided the licensee was obligated to follow them. However the licensee has the option to never intend to follow the submitted procedures. Again, such does not appear to meet the intent of the Commission's instructions.

   On the surface it appears that NRC Staff is attempting to comply with the instructions of the Commission; however, under the facade of literary gobbledygook the resulting impact of the "new" method is no different from the original version which the Commission instructed to be abandoned.

2. A draft memorandum from John G. Davis to William J. Dircks appears in the material. The memorandum states that "individuals from .... two Agreement States helped prepare this proposal". If this memorandum refers to Kirksey E. Whatley as being one of those persons, the statement is in error. Numerous comments with requests for replies have been submitted but receipt of the comments and/or consideration of the comments has never been acknowledged by Office of Nuclear Material Safety and Safeguards. Such a statement is in error and is misleading to those not familiar with the activities of the two Agreement State members of the Part 35 Taskforce in that they have not been allowed to actively participate in the development of Part 35 changes.

   It must be pointed out that until approximately the first of January 1984, no apparent effort has ever been made by NMSS Staff to obtain comments from Agreement State representatives on the Taskforce and certainly no effort was made to keep those representatives informed of actions under consideration except receiving an occasional draft change.

   Since January 1984, Mr. Norman McElroy has made several telephone contacts with Agreement State representatives which is encouraging. It is anticipated that this represents a welcome change in direction.

3. The "opponents" discussion to "Alternative 3" is interesting and misleading and in part incorrect. Does not the same "conservative" versus "liberal" reviewer statement apply to inspectors? Can this statement be interpreted to mean that a public notice will be given beforehand of whether a conservative or liberal inspector will review operations? Certainly if such a statement is applicable to licensing it is equally applicable to inspection , for if the new licensing proposal is adopted the inspector simply becomes the "license" reviewer.

   From reading this argument one might gain the opinion that deficiency letters will be eliminated with respect to applications. Does this imply that procedures will be accepted as valid even though they contain gross radiation safety problems? If the answer is no, then will not deficiency letters be written?

   That brings us back to the initial comments, that if the licensee is not obligated to follow the procedures he submits and can change them, what is the purpose of the review? It certainly appears that this new proposal is a waste of applicant's time as well as NRC Staff time.

   The "opponents" statement states that a licensee would have to submit all changes in facilities, equipment and procedures for NRC review is a conception of the individual who wrote that statement only and is not necessarily reflective of current licensing requirements or the requirements if alternative 3 is adopted.

   Changes in facilities (changing rooms) should not require amendment change unless teletherapy sources are involved. Equipment changes should not require amendment. What difference does it make if a Victoreen GM survey meter is used or an Eberline GM survey meter is used? The criteria is defined in the regulations. Such changes are not normally subject to amendment requests nor to citations by inspectors.

   However procedure changes, how such equipment is used, when such equipment is used, etc, is, and should be, subject to review.

   The statement that "he may not replace any equipment or service contractor or change any facility described" is in error and appears to be deliberately misleading. Even NRC standard conditions state "... or by other persons specifically authorized...", which currently allows any licensee to change service contractors.

   The statement that "most citations are not issued for failure to follow a certain procedure" supports the concept of requiring a licensee to follow a set of established procedures. It simply says the current sytem works.

4. Page 9 of enclosure 1 to the packet of information states that all human use requirements will be incorporated into 10 CFR Part 35. It is recognized that Part 35 does deal with human use of radioactive material. However, from a casual reading by soneone not reasonably familiar with regulatory requirements, that individual may obtain a false impression that all requirements of medical licensees are to be incorporated into one easy to find document. Such is not the case, as other Parts of 10 CFR apply.

   It is suggested that a statement be incorporated that clearly points this fact out so that the casual reader will not be under a false assumption. The NRC efforts to consolidate requirements is commendable.

5. On page 18 of enclosure 1 of the packet a disgusting, distasteful, dissertation appears on previous comments regarding the suggestion that the regulations require that the word "operable" appear before words such as "survey instrument", "room monitor", "fume hood", etc. The initial comment was made, as is the stated purpose of the proposed change, to add clarity to the regulations. Based upon inspection experience, the addition of the word operable could eliminate a lot of problems, especially from an inspector's viewpoint.

   If the word "operable" is inappropriate for use in Part 35, an explanation as to why the word is necessary in 10 CFR 34.24 is requested. The addition of the word might lengthen the regulations but that additional length should be considered.

   To clarify what "operable" means in another document (ie; statements of consideration, etc;) would defeat the purpose of placing requirements in one easy accessible document. The absence of the word is conspicuous.

6. Careful attention should be given to allowing a physician to practice nuclear medicine without being named on the license for periods which could be up to five years. The proposed changes require that the visiting physician's name appear on nuclear medicine license at the time of approval by the insititution's committee. Can the visiting physician continue to work as a "provisional authorized user" even though his name may have been removed from the license under which the committee granted "provisional user" status? The wisdom of transferring such authority to a licensed institution's radiation safety committee for such extended periods of time is questionable. It is not a question of the licensee having the responsibility to make sure that a physician in performing properly. It is a question of whether or not in a medicial setting such careful scrutiny as is needed will be administered. That can affect public health and safety.

   The original intent of this standard condition (which originated in Alabama) was to provide coverage for one or two man nuclear medicine departments while physicians were on vacation or out of service for short periods of time.

7. It is understood that NRC reviewers of Agreement State programs object when Agreement States issue two licenses to separate individuals or businesses to operate at the same location. Such objection is understandable from an inspection viewpoint.

   Does the proposal to allow mobile nuclear medicine services to operate in licensed client facilities represent a change in NRC policy related to other types of licensees?

8. Apparently there are several differing philosophies regarding the purpose of performing contamination surveys. This differing philosophy accounts for the difference in concerns as expressed in previous correspondence. From statements contained on page 42 of enclosure 1, a discussion of 35.70, it appears that NRC's concern is whether or not adequate controls or safety measures are being used. This is a good reason for performing contamination surveys. However, it remains questionable as to whether or not "once each week" surveys will provide the needed information in light of the admission that "the Commission knows that a wipe test made several days after spillage... will probably not detect any contamination".

Wipe tests need to be more than a check on controls and safety measures. The users of radioactive material should be aware of the potential hazards (levels of contamination) in their working areas from a safety standpoint, not only a management control technique. There is a great difference! Surveys performed once each week, at the end of work on Friday as an example, are of little value except to provide an inspector a record to look at.

It is refreshing to see that 35.70 was expanded to include contamination surveys and requirements for levels of action since previous drafts provided minimal and inadequate requirements for surveys.

9. Again the comment is made regarding a mobile nuclear medicine licensee's area of use in a client facility being considered an unrestricted area due to his inability to control access to areas of use.

   A letter of authorization from each mobile nuclear medicine licensee's client should accompany any request to use radioactive material at the client's address. Such letter of authorization should provide the licensee authority to control access to areas of use.

   If any licensee cannot control his area of use of radioactive material and cannot control the area for radiation protection purposes, his license should be terminated. The definition of restricted area should be looked at as well as permissible levels of radiation in unrestricted areas.

   It is recognized that the mobile licensee is limited to unit dose syringes and vials and that resultant radiation levels from such sources are easily controlled. That argument is not justification for this exception.

10. The discussion of 35.620 on page 54 of enclosure 1, states that "the licensee needs a survey instrument on hand in order to measure exposure rates in the case the radiation monitoring device or the teletherapy unit fails. It is pointed out that wording in proposed change 35.620 would permit the use of a survey meter with a maximum range of 1 mR per hour to be used for the purpose of "measuring exposure rates" in case a teletherapy unit fails. It is recommended that this proposed change be re-evaluated.

11. The following comments are offered on specific sections of the proposed changes:

    a. Section 35.18. A licensee is required to notify the Commission within 30 days of the permanent discontinuance of an authorized user. The intent is to assure that the licensee has at least one authorized user remains in active practice. It is recommended that if a visiting physician practices more than 60 days, the Commission be notified also. Such would not require an immediate amendment.

    b. Section 35.30. "All authorized users must participate in the establishment...of the program...Committee." It is recommended that the wording be reviewed since physicians added to a license after the program has been established can in no way participate in its establishment.

obviously all (who are present)

c. Section 35.50 and other sections. This section and several others require that the radiation safety officer sign numerous records such as daily checks on dose calibrators. One of the stated objectives to the revision of Part 35 was to reduce paper work on licensees. The necessity of having the RSO sign routine, day-to-day generated documents is questioned and is likely to become a matter of routine without any meaning. A more practical approach would appear to require the person performing the test to make the record and initial the record and notify the RSO of test results outside an established range. Then, perhaps on a weekly basis, require the RSO to review the weeks test results for trends.

d. Section 35.51(a). This section requires that the licensee calibrate survey instruments. Wording of this section should be reviewed to permit licensee's to use calibration services other than their own. As worded the licensee shall calibrate.

e. Section 35.51(b)(2). This section requires that two readings on each scale (as appropriate) be calibrated. Again a stated objective of the change was to incorporate all nuclear medicine requirements into Part 35. It is recommended that this section be revised to read as follows:

(2) Calibrate two points, separated by 50% of the scale, on each scale that must be calibrated.

In any case, it is difficult to calibrate a reading.

f. Section 35.51(d). Dedicated check source should be defined if such a term is used. Since both low level GM survey meters and ionization chambers are required to be used, dedicated check sources should be clearly defined as are sources designed to check dose calibrators.

g. Section 35.59(h). The need and/or purpose of surveying the storage areas of brachytherapy sources with a low range survey meter is not understood. What is a licensee required to survey for? Contamination? Exposure rates? Or what?

h. Section 35.62. It is recommended that the words "to be administered" be dropped from this section. "To be administered" has nothing to do with needed labels on syringes. All syringes of radioactive material are not intended to be administered (ie; calibration of instruments); however, all should be labeled.

This section is intended for misadministration problems and a requirement that all syringes be labeled would appear to strengthen the intent.

i. Section 35.63. The comments on 35.62 above would appear to apply to 35.63 also.

j. Section 35.70(c). It is recommended that the wording of this section be reviewed. If the section is requiring that licensees be able to measure exposure rates as low as 0.1 mR per hour, perhaps it can be better worded. If a licensee uses a survey meter that has a minimum scale of 1R per hour, he can measure exposure rates greater than 0.1 mR per hour. He simply can't measure exposure rates from 0.1 mR per hour up to 1R per hour.

k. Section 35.70(e). This section has previously been commented on. This writer does not consider weekly contamination surveys to be adequate. Here again the purpose of performing surveys is apparently not agreed upon.

l. Section 35.70(f). Relating contamination limits to disintegrations per minute in most nuclear medicine departments is impracticable. Few facilities have the equipment, the needed reference standards, or the knowledge of determining efficiency of detectors and converting cpm to dpm. A more logical approach would appear to relate contamination limits on wipes to "radiation free" background levels. ("Radiation free" is understood in the context of measuring contamination on wipe samples with full recognition that no area is radiation free).

m. Section 35.70(g). Once the individual notifies the RSO that contamination exceeds the action level, what does the RSO do? Reference should be made to 35.31 (b)(2)(vi).

n. Section 35.80(e). Wording or intent of this survey is not clear and has been commented on before. Perhaps better wording would be "prior to departure from client facilities, the licensee shall survey with a low range survey meter all areas in which radiopharmaceuticals were used to ensure that all radiopharmaceuticals and all associated waste have been removed."

o. Section 35.92. Numerous comments have been offered regarding not being able to hold material with a half-life greater than 65 days for decay. Please refer to previous comments.

p. Section 35.315(f). It is recommended that the words, "the patient's room" be inserted between the words survey and for in the first line (ie; "...survey the patient's room for..."). This will make 35.315(f) consistent with 35.315(e).

q. Section 35.315(f). The comments regarding "dpm" offered in comment 11.1 apply here also.

r. Section 35.406. Brachytherapy sources are not always immediately returned to their place of storage. An inventory should be made at the time of removal. Time plays an important factor in the probability of recovery of lost sources.

s. Section 35.420. This section fails to require the possession of a low range survey meter. Licensee's using brachytherapy sources are required to use low range survey meters in performing surveys required by 35.59(h).

t. Section 35.620. This section, as currently worded, authorizes the use of a 1 mR per hour low level survey meter to measure exposure rates in case the monitoring device or the teletherapy unit fails. A licensee could possess only a 1 mR per hour survey meter and be in compliance. Such a meter to measure exposure rates in case a teletherapy unit fails is unacceptable.

u. Section 35.621. It is recommended that the wording of this section be revised to read as follows:

"Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that has resulted in an exposed or partially exposed source. The .... room".

A radiation monitoring device cannot predict a malfunction that may result in an exposed or partially exposed source.

v. Section 35.621. It is recommended that the radiation monitoring device be visible with a viewing system so that the device can be observed without entering the room. Section 35.621(e) requires that the licensee maintain a daily record which indicates that the device works when the source is exposed. Assuming door interlocks work and no viewing system for the monitoring device is present, the only way to check the monitoring device while the source is on is to be in the room or by-pass interlocks.

w. Section 35.630, 35.63 and 35.633. These sections require that the licensee perform numerous tests. The current wording does not permit the licensee to use consultants. Wording should be changed to permit consultants to perform this work.

x. Section 35.633(d). Here again this section in the first paragraph requires that the licensee perform measurements. In the next sentence the section implies that the qualified expert may be able to perform spot-check measurements. Clarification or the use of "plain English" should be used. Exactly what is meant?

y. Section 35.641(v). The State of Alabama has been corresponding with the Agreements State Branch of NRC for the past year about problems associated with the words as currently exist in 35.641(1). It is requested that this requirement be carefully reviewed in light of problems associated with determining compliance.

z. Section 35.641(c). In this section the following sentence segment appears:

"... the measured exposure rate at several points in each expressed in millirem per hour...."

Please review the use of the term millirem to measure exposure rate.

aa. Section 35.900. Provisions are made for physicians to be considered as authorized users even though those physicians do not technically meet qualifications to the "nth" degree. It is recommended that similar consideration be given to radiation safety officers.

bb. The following typographical errors are pointed out:

i. Page 17 of enclosure 1, 5th line from "because".

ii. Page 105, Section 35.70(f), problem with spacing of words.

iii. Page 115, Section 35.315(d), suggest "RSO" be spelled out.

iv. Page 120, Section 35.605, suggest "NRC" be spelled out.

v. Page 133, Section 35.644, third line, suggest "roentgen".

vi. Page 119, Section 35.520, last line (and other locations also). The word "part" is sometimes started with "P" as in 35.644, and sometimes with "p" as on page 119.

12. On page 7 of the "Draft Commission Paper" under discussion of alternative 1, the following statement appears:

> "The staff is not aware of anyone who would recommend retaining the current Part 35 over the proposed regulation".

While the statement may be true "that the staff is not aware", the statement in itself implies a lack of sensitivity to expressions expressed by numerous individuals in writing and even before the Commissioners in public hearing. The revision of Part 35 is applauded to the extent of the revision. However the new proposed methods of implementation have been objected to and criticized by numerous individuals - even by the Commission in its rejection of the original staff proposal.

It is the opinion of this writer that many individuals and most Agreement State Program Directors would favor retaining the current system if the alternative is the proposed method of implementation.

13. Several Statements in the "Regulatory Analysis" are misleading. As an example:

> "If no action is taken, the staff believes the industry will continue to be confused about whether a specific standard is a requirement or a suggestion".

If Part 35 is adopted as NRC staff has proposed (with certain changes) industry should not be confused. That's the purpose of the change to Part 35. The revisions to Part 35, if adopted, as alternative 3, could achieve the goal of removing confusion in industry while retaining what many believe to be necessary, established procedures for radiation safety.