AA73-1
PDR
C.4

SUMMARY OF COMMENTS ON PROPOSED REVISION OF
10 CFR PART 35 THAT WAS DISTRIBUTED FOR
COMMENT ON FEBRUARY 13, 1984

Commenters:

| | |
|---|---|
| OPE | Memo Cunningham/Jupiter dated March 19, 1984 |
| IE | Memo Cunningham/Grace dated March 21, 1984 |
| ADM | Memo Cunningham/Norry dated March 28, 1984 |
| RM | Memo McElroy/Clark (Cost Analysis Group) dated April 6, 1984 |
| RES | Memo Cunningham/Goller dated May 10, 1984 |
| SP | Memo Cunningham/Kerr dated April 26, 1984 |
| RI | Memo Cunningham/Martin dated March 30, 1984 |
| RII | Memo Cunningham/Stohr dated April 6, 1984 |
| RIII | Memo Cunningham/Hind dated March 30, 1984 |
| RIV | Memo Cunningham/Bangart dated April 2, 1984 |
| RV | Memo Cunningham/Scarano dated April 6, 1984 |
| M | Memo Glenn/Mallett dated January 11, 1984 |
| G | Memo McElroy/Glenn dated January 20, 1984 |
| P | Memo Glenn/Potter dated January 11, 1984 |
| NV | Letter Nussbaumer/Vaden dated March 13, 1984 |
| ND | Letter Nussbaumer/Mount dated March 22, 1984 |
| OR | Letter McElroy/Blazek dated March 23, 1984 |
| AL | Letter McElroy/Blazek dated March 23, 1984, with attached comments by Whatley |
| NM | Letter Nussbaumer/Garcia dated March 23, 1984 |
| GA1 | Letter Blazek/Connell dated March 23, 1984 |
| GA2 | Letter Nussbaumer/Rutledge dated April 2, 1984 |
| CRCPD | Letter McElroy/Hazle, Chairman, Conference of Radiation Control Program Directors, dated March 29, 1984 |
| TN | Letter Nussbaumer/Graves dated April 19, 1984 |
| CO | Letter Nussbaumer/Hazle dated April 11, 1984 |
| TX | Letter Nussbaumer/Lacker dated April 23, 1984 |





Enclosure 8

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|---|---|
| AZ | Letter Nussbaumer/Tedford dated April 24, 1984 |
| RIb | Briefing Region I/McElroy held March 9, 1984 |
| RIIb | Briefing Region II/McElroy held March 20, 1984 |
| RIIIb | Briefing Region III/McElroy held March 23, 1984 |
| RIVb | Briefing Region IV/McElroy held March 21, 1984 |
| RVb | Briefing Region V/McElroy held March 22, 1984 |

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Comment: In the staff paper, it appears NRC has already selected Alternative 2 and the request for comments is a perfunctory act.

Response: The staff has decided to recommend Alternative 2 to the Commission. The staff has asked for comment because the proposal may have unintended or unknown consequences, or other persons may have additional or alternative suggestions. Each comment has been read and considered. Many valuable comments have been incorporated in the package. We have not received any comments that lead us to believe that the basic proposal is flawed.

Comment: If 40% of applications that are now received are deficient, doesn't this indicate that a lot of applicants don't have adequate training? Aren't you just turning your back on a big problem?

Response: No. Many requirements are in standard license condition and branch policy statements that are not generally available to the public. There are many essential safety elements in the application guide that are required of all licensees (despite the front-page disclaimer that "compliance with regulatory guides is not required"). Because the applicants don't know all the rules governing the review and approval of applications, it should come as no surprise that many applications are deficient.

We believe the unannounced inspection is a better proficiency test. Inspection results for 1982 are summarized in Enclosure 9. Almost all of the 1240 citations issued in 1982 are for items that are better described as early signs of safety program degredation, but that do not present a worker or public safety hazard.

Comment: Some of the "essential safety elements" are guidelines. The application is like house plans to show compliance with the building code. There is no need to standardize all houses. You are trying to make all hospitals look alike.

Response: The analogy is excellent. (Many radiation safety experts would disagree with your suggestion that in some cases we have codified "good practice." In most cases we have been chastised for leaving something out.) Once you have a building permit for a house, you may make minor changes in room layout or

design that are consistent with the building code. The "building standards" office relies on inspectors in the field to determine compliance with the code and workmanship standards, but not the architect's detail drawings or decorator items.

Comment: Are you saying that the licensing process is no longer important?

Response: No. We do, however, believe that the licensing process carries too much responsibility in the regulatory program. Its role in the medical industry should be reduced. The inspector is best situated to determine whether a program is operated within the requirements.

Comment: The proposed Alternative 2 would be acceptable if (among other things) the licensee were only allowed to modify procedures for which requirements are identified in the regulation.

Response: No. The actions that require a license amendment (new users, new locations, and new types of use), are identified in the regulation. We contend that the essential safety elements of all required radiation safety procedures are identified in the regulation. Other elements that may be identified in written procedures are not of significant radiation health and safety concern.

Comment: Inspectors will spend more time reviewing procedures in the field. Sometimes there are evolutionary equipment or procedure changes that are better evaluated in the office. Also, in addition to having to familiarize themselves with programs on the spot, inspectors will have to spend a lot of time on followup inspections.

Response: Watching a worker do something is quicker and more relevant to safety than reading what he is supposed to do. The evolutionary changes in safety equipment that you refer to are very infrequent. A detailed review and approval process is a very costly way of assuring that things won't be done incorrectly. For the level of hazard of materials that are authorized, that expense does not seem to be justified. Once something has been done incorrectly, whether in violation of regulation or procedure, a lot of inspection and licensing time is consumed.

Comment: Clarify that we lose a "safety valve" if there is no procedures modification review mechanism exercised by a regulatory agency.

Response: The statement is the closing sentence of "Objections-Alternative 2" of the staff paper.

Comment: The regulation does not clearly provide for a citation for a failure to follow procedures.

Response: Yes, it does. The licensee, through the RSO, must implement the procedures. Implement means, "to carry out, accomplish, or ensure fulfillment

of." If the procedure which was implemented to meet a requirement has not been followed, the citation may be issued for failure to comply with the regulation.

Comment: You say that savings in amendment fees under your proposed Alternative 2 are insignificant and yet you say that "the effect of selecting Alternative 3" is costly to both NRC and licensees. From these statements, it is difficult to understand why you have chosen to recommend Alternative 2 when there is no disadvantage to Alternative 3.

Response: The disadvantage of Alternative 3 is that the model procedures in the licensing guide become, for practical purposes, regulations. The savings in amendment fees is what is insignificant to both individual licensees and the industry as a whole (one or two thousand amendments per year from the entire industry, at $120 each). Alternative 3 is costly to NRC because the fee does not cover the expense of reviewing the request and these reviews consume staff time that could be more productively spent on other projects that have greater impact on public health and safety. The NRC review is expensive for licensees because it adds the following costs: transmittal letter, paperwork involved in issuing a check to pay for the amendment, and whatever expenses might be incurred while awaiting the authorization to make the requested changes.

Comment: The Commission's instruction that the staff should approve licensees' procedures has been ignored. When the Commission said, "continue the pre-licensing review of the applicants' operating procedures," it meant more than a review for the sake of reviewing.

Response: In the earlier submission the staff had proposed that the applicant merely certify that it had adequate procedures, not be required to submit them for review. Therefore, the word "pre-licensing" is an important modifier in the instruction.

Comment: When discussing Alternative 1 in the staff paper, you say you were not aware of anyone who would retain the current regulation over the proposed regulation. In fact, many individuals would retain the current system in favor of Alternative 2.

Response: You are correct. But most persons who disagree with this proposal recommend the proposal described in Alternative 3, which is an alternative licensing method based on the same set of regulations. Of all of the NRC,

Agreement State, and informal industry comments received, only a handful of persons have clearly recommended retention of the current Part 35 over the codification provided in the proposal.

This is not to suggest we are taking votes. Rather, it appears that almost everyone who has seen the package falls into one of two camps: (1) publish the package for comment, or (2) modify the package to require NRC approval of equipment, rooms, and procedures and changes thereto (or some combination of those three), and then publish the package for comment.

There are five principal levels of regulation:

1. Registration: Send in your name and address.
2. Self-certification: Promise you will follow the regulations.
3. Commitment: To get a license, describe your program. If your needs change, you may make the changes to your program that are consistent with your license and the regulations.
4. Control by license: To get a license, describe your program. If your needs change, get NRC permission before making program changes.
5. Supervision: Operate your program under the direct personal supervision of an NRC inspector.

Level 1 does not provide an adequate assurance of public health and safety for the materials used in medical programs. The staff recommended Level 2 in the April 1983 submission and the Commissioners rejected it. Level 3 appears in this package as Alternative 2, and is recommended by the staff. Level 4 appears in the package as Alternative 3. When weighed against the benefit to society, Level 5 is too costly.

Comment: You say industry is confused about whether a specific standard is a requirement or a suggestion. If NRC selected Alternative 3, industry would no longer be confused and you would retain what many believe are necessary procedures for radiation safety.

Response: For the purpose of this discussion, we may say NRC has two kinds of standards: (1) regulations, license conditions, and orders, and (2) regulatory guides. Failure to comply with the first standards can result in citations,

fines, or imprisonment. There is no penalty for not complying with a regulatory guide procedure because it is an example of a way of achieving compliance with the regulations. We contend that the essential elements of the medical radiation safety procedures have been codified in the regulation, and what has not been codified is not of great safety significance. To adopt Alternative 3 would require NRC staff to review changes that are not of great safety significance. The confusion as to the status of regulatory guide procedures would remain unresolved.

Comment: Contrary to what you say, Alternative 1 (no action) does provide more safety than Alternative 2 because in many cases the application review process is a learning experience for the applicant. It is easier to prevent a problem than it is to clean up afterward.

Response: The application review process you refer to is retained in this draft.

## CHANGES IN PROCEDURES

Comment: Inspectors will have to spend more time in the field reviewing procedures because this will not be done during the licensing process. Inspectors will have neither the time nor the reference materials needed in order to make an adequate review.

Response: Inspectors should not review written procedures in the field. They should watch workers working, and spot-check records for completeness. A procedure is a written description of what a worker will or will not do. The thing that is important is what a worker actually does or does not do.

Comment: Why should the licensing staff spend its time reviewing procedures if they won't be enforceable?

Response: The pre-licensing review provides for a finding of acceptable training and experience, facilities and equipment, and a management commitment to safety.

Comment: Contrary to what you say, under the current licensing system, licensees do not have to get an amendment before changing the equipment they use.

Comment: Changing rooms where byproduct material is used should not require an amendment.

Comment: Changing rooms should require a license amendment.

Response: A licensee might identify equipment by name and serial number and rooms by number that will be used for storage or use of byproduct material in an application. The Office of the Executive Legal Director advises that, if a licensee makes changes to equipment and rooms it has specifically designated, it is no longer in compliance with the requirement to conduct its program in accordance with representations in the application. Therefore under the current licensing system, the licensee must get an amendment before making changes. Similarly, the licensee must get an amendment to use additional rooms for its byproduct materials program, or to reduce the floor space associated with the program, in order to respond to changes in patient load level, available equipment, and space needs. The proposed system would allow licensees to make changes. They would have to document the changes as described in new § 35.36.

Comment: Although the draft regulation requires the implementation of written procedures, there is no standard for minimum content, nor a requirement that modified procedures be similar to those submitted for NRC review. This complicates inspection and enforcement.

Response: Minimum procedure content is specified in the regulation for almost all the procedures required. (See Sections 35.30, 35.32, 35.33, 35.34, 35.37, 35.38, 35.50, 35.51, 35.53, 35.59, 35.70, 35.75, 35.80, 35.92, 35.204, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.610, 35.621, 35.630, 35.632, 35.633, 35.641, 35.642, and 35.645.) There is no need for modified procedures to be similar to original procedures. There is a regulatory requirement that the licensee's activities be in accord with its procedures and the regulations.

Comment: Licensees could follow technically invalid procedures for several years because of our low inspection frequency. Inspection time, fines, shutdowns, and possibly even worker dose will increase. Inspections will have to be more frequent.

Response: The alternative you recommend, the NRC review and approval of changes, is expensive and time consuming for both the licensee and NRC, and does not provide assurance of safe use. Only an unannounced inspection can do that. Because all inspectors will be working from a single codified 30-page regulation, inspections of compliant licensees should be quicker. Total NRC time spent on non-compliant licensees should be reduced because NRC will be looking at the end product rather than the planned process. We disagree with the perceived need for more frequent inspections.

Comment: Many citations are for not following procedures that licensees said they would follow. Why is it acceptable for applicants to say they will follow a procedure from a guide?

Response: If a licensee is planning on willful negligence, the prior submission of a long application is unlikely to deter it, while it unnecessarily increases the application burden on others. Almost all procedure citations are for not doing anything when something is required, or for doing something that is clearly prohibited.

Comment: You should require clear, separate documentation of changes. What is to prevent the licensee from changing its procedures even as the inspector is conducting his review?

Response: A new Section 35.36, has been added. It requires the licensee to conduct a formal review and approval process before making any procedure changes.

Comment: The internal review process that you require would not be a real review because the authorized user who is proposing the change may be the only radiation expert in the hospital.

Response: This is noted in the staff paper section "Alternative 2--Objections"; also, see the response in "Alternative 2--Proponents."

Comment: Today, about 40% of licensing requests are deficient; yet, you say there will be no further need for deficiency letters. Do you mean to say that procedures must be accepted as valid even though they contain gross radiation and safety problems?

Response: Deficiency letters currently issued are necessitated in large part because requirements are buried in Part 35, or are in license conditions and branch policy statements that are not generally available to the public, or regulatory guides that are purported to be for guidance only. By codifying all the requirements in one place, the applicant can use the regulation as a checklist to determine whether his application is complete. If it is, it is less likely that a deficiency letter will be needed. If an applicant submits an inadequate application, a deficiency letter will be issued.

Comment: You should only allow changes in procedures that will not decrease the effectiveness of the licensee's radiation safety program.

Response: The phrase "if the modification does not reduce the program effectiveness and meets Title 10 requirements" has been suggested before. A licensee may design a very safe program that is too expensive or too inflexible to meet changing patient care needs. It should not have to pay an amendment fee to modify its program as long as it continues to meet the regulatory standards.

Comment: You should develop evaluation criteria that the licensee must use to measure the effect of proposed changes.

Response: A new regulatory guide appendix has been developed that lists things that should be considered when evaluating proposed changes. However, it does not have standards to actually "measure the effect of changes."

Comment: In the cost analysis you should estimate: how many licensees are represented by each "hypothetical licensee"; the increase in burden due to the rule; the burden of the other alternatives described in the Commission paper; and the NRC staff retraining cost.

Response: Done.

Comment: You say there is no negative impact on small entities, yet, for your hypothetical licensees, the additional costs will range from $1,600 to $13,000. Also, an extra 400 to 600 technician hours will be needed for each licensee.

Response: The numbers you cite are the total regulatory burden; they do not represent new costs. Enclosure 4 has been revised to show total burden and new burden.

Comment: Licensees should be required to keep all records since the last inspection, or at least longer than just 2 years.

Response: No. The Office of Management and Budget (OMB) must approve record retention requirements. In response to that requirement, the Office of Administration has prepared a draft record retention rulemaking that establishes uniform retention periods of 2, 5, or 10 years or life of the license or piece of equipment. This Part 35 draft is consistent with that policy. Your suggestion is essentially an open-ended retention period; OMB does not allow them without good cause.

Comment: Why must the licensee record patient identification information on the dosage log sheet? The dosage is recorded in the patient's treatment record.

Response: Not all licensees record dosages in patients' files. The intent of the requirement is to reduce the chance of misadministrations by checking both name and identification number.

Comment: Many sections require that the radiation safety officer sign numerous records such as daily checks on dose calibrators. One of the stated objectives for 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 it and notify the RSO of test results outside an established range. Then the RSO could review records on a weekly basis.

Response: The RSO does not sign the daily checks you refer to. The individual who makes the check initials it. The RSO generally does not sign routine, day-to-day records; usually, whoever creates the day-to-day record initials it. It is the licensee's responsibility to establish whatever management mechanism is needed to ensure management intervention when trigger levels are exceeded. A specified frequency of review was considered but not included because of the range of licensee program sizes.

Comment: Your record retention period that pertains to patient dosage records may be shorter than the retention period required by State law. These records

should be retained indefinitely, or as long as required by other applicable law.

Response: No. The licensee bears the burden of ensuring compliance with other laws that regulate its activities. The NRC cannot tailor its regulations to suit each State's medical regulations, nor can it say, "Keep a record as long as someone else makes you," because that does not provide a clear or meaningful standard.

Comment: In listing information collection requirements, you have required more than what is reasonably needed for radiation safety. This kind of information should be mentioned in a regulatory guide, but not in a regulation.

Response: Your point is well taken, but the burden is balanced by the fact that each listing does provide an explicit checklist of what the NRC considers elements of an adequate record. No changes have been made.

Comment: You should use the word "operable" to describe survey meters and other equipment.

Response: No. The word does not add to enforceability. The statement of consideration provides unambiguous notice that equipment that isn't working cannot be used to meet safety requirements.

Comment: Please clarify what you mean by a "dedicated" check source.

Response: Done. See the preamble section entitled "Notes."

Comment: "Management" should be defined to include "or designee."

Comment: By requiring the "licensee" to calibrate the survey meters, you preclude the use of calibration services.

Response: Legal staff advises that "designee" is implied in legal construction of the term "licensee." For instance, a licensee may be a non-living business entity; thus the wording of the requirement places a legal responsibility on the licensee that may be fulfilled by full- or part-time employees or perhaps by contractors. See the preamble section entitled "Notes."

Comment: Your notes on word usage should be codified in the regulation.

Response: No. The regulation contains the definitions needed to clarify the requirements. The word usage notes will be published, along with an edited statement of considerations, in the regulatory guide in case questions of regulatory intent or interpretation come up at a later date.

Comment: Define "promptly."

Response: No. When used with its normal definition ("performed readily or immediately"), legal staff advises that a word need not be defined in the regulations. Contrast the word "person" which is defined in Part 30 because it

is used in other than its normal definition (a legal definition of a business or government entity rather than the normal "An individual human being").

## LICENSEE MANAGEMENT

Comment: There should be some kind of ALARA program for all licensees, not just medical institutions. The draft Part 20 requires one.

Response: No. The ALARA program elements in the regulation may be generally characterized as steps to ensure information flow between managers with overlapping responsibilities. At a non-institutional licensee, such formalized communication is unnecessary. If Part 20 is revised, incompatibilities will be resolved at that time.

Comment: You should require that mobile service licensees include authorized users on the management team. This will ensure appropriate management control.

Response: For the level of hazard of materials authorized, there does not appear to be a strong need for NRC to dictate corporate organization.

## RADIATION SAFETY OFFICER AND RADIATION SAFETY COMMITTEE

Comment: You should clarify the responsibilities that must be borne by the radiation safety officer and by consultant radiation safety officers.

Response: Whether consultant or full-time, the regulations require the licensee's management to provide a statement of authority, a list of duties, and provision of adequate resources. The degree of specificity you suggest is inappropriate for two reasons: (1) Some safety tasks don't apply to all licensees; and (2) if you leave an important task out, the courts assume you did so purposefully since you took the time to go to such great detail.

Comment: Clarify how many physicians must be on the radiation safety committee.

Response: If one physician is authorized to use all materials listed on the license, he is the only one needed. If one physician is authorized to use materials for nuclear medicine and another physician conducts teletherapy, both must be on the committee. Alternative wording is invited.

Comment: Why must committee minutes note the numerical results of ballots?

Response: The requirement was suggested because it is the one quantitative measure of committee concurrence that is easily recorded.

Comment: If the radiation safety committee only reviews a user's credentials "on the basis of safety," that will be an incomplete review.

Response: Agreed. The requirement has been revised to include "and in comparison to the training and experience standards in Subpart J of this part."

Comment: You could develop a more concise rule if you simply designated the private practice authorized user as the radiation safety officer and radiation safety committee.

Response: Correct, but then he would have to be exempted from the formal ALARA program requirement and the committee meeting requirements. Conciseness may be purchased at the expense of clarity. No changes have been made.

Comment: The standard of accuracy for the dose calibrator that you list in the Draft Regulatory Guide is more stringent than the requirement in the regulation. Which standard applies?

Response: The regulatory guide procedure provides a trigger level that initiates equipment repair before the licensee goes out of compliance with the regulation. If a licensee has adopted the guide standard and has not initiated repair after going outside the range allowed in the guide standard, it is out of compliance because it has not implemented the procedure. If it has not initiated the repair after going outside the regulatory standard, it is out of compliance with the regulation.

Comment: Many licensees who have pre-measured unit dosages don't believe they need a dose calibrator. Physicians don't test the potency of non-radioactive drugs that they administer to patients.

Response: Other drugs don't decay with time the way radiopharmaceuticals do. A dose calibrator only costs about $2,000. It takes only a few seconds to measure each dosage. The NRC's Advisory Committee on the Medical Use of Isotopes has recommended that all radiopharmaceutical licensees be required to use a dose calibrator to measure dosages.

Comment: The dose calibrator linearity should only be tested to the highest dosage ordinarily measured, not the highest dosage ever measured.

Response: No. Therapy dosages, which are not ordinarily measured because they are not frequently administered, are ten-fold higher than diagnostic dosages. The linearity test provides the only assurance that the higher measure is accurate.

Comment: If the dose calibrator manufacturer supplies geometry dependence test results, there is no need for the licensee to repeat the test.

Response: If the detector was internally damaged in transit from the distributor to the receiver, the manufacturer's test result would no longer be valid.

Comment: The NRC should publish a position statement on the temporary use of radiopharmaceuticals without measuring the dosage in those cases where the licensee's dose calibrator is broken.

Response: Agreed. However, it will be developed independent of this project.

Comment: You should require that the dose calibrator be tested for accuracy with sources similar in energy to the materials that will be assayed.

Response: Done.

Comment: You should require that daily dose calibrator constancy checks be made with low, medium, and high energy sources. The proposed requirement is much less stringent than our current guidance.

Response: The daily constancy check in this draft is based on Section 4.5.1 of the ANSI standard for dose calibrators. Our current regulatory practice goes beyond the recommended requirement.

Comment: You should require that the dose calibrator be tested for linearity from zero to the highest activity measured.

Response: ANSI Section 4.2.2 says "Calibration of the equipment should cover as completely as practicable the activity ranges for which it will be used, particularly those ranges of activity of radionuclides to be administered to patients." There is no public health and safety need to check for linearity of measurement ranges that are not used to measure patient dosages. This may cause unnecessary worker dose.

The chairman of the ANSI N42.13 drafting committee indicated in conversation that the majority of the committee recommended that the calibrator only be tested for linearity up to the highest dosage administered.

## SURVEY METERS

Comment: When calibrating survey meters, the licensee should be required to use a nuclide source whose activity is known within 5%.

Response: No. Survey instruments can also be calibrated with X-ray machines. When calibrating with nuclide sources, the activity is not the descriptor of interest--the dose rate at a specified distance, which depends on how the source is fabricated and encapsulated, is what is important.

Comment: Require that licensees use a low range, thin-end-window survey meter when making surveys in the nuclear medicine clinic.

Response: No. The licensee bears the responsibility of selecting equipment that is capable of making the measurements required.

Comment: Require that survey meters be calibrated on each scale at two points that are separated by 50%.

Response: No. All of the citations for survey meter calibration that were issued in 1982 (see Enclosure 9) were for failure to calibrate the instrument, not for calibrating it incorrectly. This continues to be the case with the current citations.

Comment: Why do you require the high range survey instrument to be an ionization type of survey meter?

Response: Only an ionization chamber survey instrument is actually capable of measuring exposure rates. See NCRP Report 57, Paragraph 3.2.4.1.

## SYRINGE SHIELDS AND OTHER SAFETY PRECAUTIONS

Comment: You should require that the licensee use syringe shields when preparing kits.

Response: That was the intent. The wording has been clarified.

Comment: You should require that technicians use syringe shields when drawing dosages out of multidose vials. For 20 millicuries of Tc-99m in 2 cc, the finger dose rate is 0.6 rem per minute. If a technician draws 10 dosages each day, and each withdrawal takes 10 seconds, the technician will get 1 rem each day to the finger. A syringe shield will reduce this by a factor of about 100.

Response: The recommendation to use syringe shields when drawing dosages has not been included.

It appears all of your dose rates came from Barrall and Smith (B&S) AAPM Monograph 1, 1976. Nuclear medicine technicians do not hold syringes as in B&S Figure 1; common practice is to hold the back half of the barrel where there is no radioactivity; the 2 cc dosage volume they use is out of date (see HP v. 41, n. 3, p. 535, Figure 1, -- 1 cc is a more representative number).

For the dose per year to the tip of the finger, assuming 1 mR/mCi-min (HP p. 538, average value for unshielded index finger; compare B&S p. 84, position 4 measure of 1,100 mR/hr for 20 mCi that is equivalent to 0.9 mR/mCi-min), average dosages of 10 mCi (New England Nuclear catalogue: MDP 10 to 20 mCi; gluceptate 10-20 mCi; MAA 1-4 mCi; pertechnetate for brain 10-20 mCi, thyroid 1-10 mCi, blood pool 10-30 mCi), 10 dosages per day (your number), 0.2 min per dosage (12 sec, you said 10 sec), and 250 days per year, the estimated fingertip dose per year due to drawing dosages is:

$$\frac{1\ \text{mR}}{\text{mCi-min}} \times \frac{10\ \text{mCi}}{\text{dosage-draw}} \times \frac{0.2\ \text{min}}{\text{draw}} \times \frac{10\ \text{dosages}}{\text{da}} \times \frac{250\ \text{da}}{\text{yr}} = \frac{5\ \text{rem}}{\text{yr}}$$

One may respond by saying that we can save the 5 rem per year dose with a one-time purchase of a $200 syringe shield. However, the first thing the technician

would do after drawing the dosage is remove it from the shield to measure it. If the dosage is high or low, the next step would be to put the syringe back in the shield to return it to the vial and adjust the volume, and then remove the syringe again to remeasure it. It appears the increased handling will consume most of the projected dose savings, rendering the expenditure unproductive.

Comment: You should require that technicians who handle radiopharmaceuticals must wear laboratory coats and gloves.

Response: No. Gloves and laboratory coats do not provide a significant barrier against contamination, and sometimes actually cause the spread of contamination instead of helping to contain it.

## SUPERVISION

Comment: The "supervision" section that requires the physical presence of the authorized user on one hour's notice seems unduly stringent. Other hospital personnel can take care of the patient, and the technician can clean up spills.

Comment: In addition to the authorized user, the radiation safety officer should also be immediately available and physically present on one hour's notice.

Response: The requirement that the authorized user be physically present given one hour's notice provides for proper response to spills and losses, appropriate response in case there are medical implications involved in an emergency, and active authorized user oversight of supervised individuals by requiring geographic proximity. (This will eliminate a user in one State "supervising" someone in another State.) If there is a clear public need, for example in the more expansive western states, the license reviewer may provide relief by exemption from this requirement. There is no clear need to require both to be available.

Comment: The licensee should review the procedures that an authorized user will use for supervising workers, and the qualifications of the workers.

Response: Such a requirement would represent a major policy shift with implications for other industries that are regulated by the NRC, and is therefore outside the scope of this project.

Comment: List those duties that can be delegated and those duties that cannot be delegated.

Response: In an early draft, we tried to list delegable duties and found that the list was more confusing than the simple direction to exercise supervision. The listing would most probably be incomplete for some licensees and too permissive for others.

## SURVEYS

Comment: Will the applicant specify contamination action levels in his application?

Response: No. The Radiation Safety Officer will set the levels; see Section 35.70(d).

Comment: If high contamination levels are found during a contamination survey, the surveyer should take immediate steps to prevent the spread of contamination.

Response: No. Immediate notification of the Radiation Safety Officer, who is best suited to oversee the control and cleanup of the spilled material, is required.

Comment: Many licensees use a survey instrument to assay contamination wipe samples. Provide the guidelines on converting cpm or mr/hr to dpm.

Response: Done. More information has been provided in the regulatory guide.

Comment: The permissible contamination limit in patient rooms that are about to be released for unlimited use is too high.

Response: A wording mistake was made in the earlier draft. The limit is 200 dpm/100 $cm^2$.

Comment: Weekly removable contamination surveys do not provide workers with adequate awareness of potential hazards. They should be made more frequently.

Response: Many of these surveys yield results that are below the NRC's recommended action levels. For the level of hazard caused by surface contamination in nuclear medicine hot labs, it is difficult to defend a more frequent survey.

Comment: Most nuclear medicine departments cannot measure DPM on wipe samples. Instead they should be required to refer their removable contamination measurements to background count rates.

Response: That kind of standard ignores the efficiency dependence of the detector used to measure the wipe sample. The proper units for surface contamination standards are dpm/$cm^2$ and measurements must be recorded in those units.

Comment: 200 dpm/100 $cm^2$ is too restrictive a contamination limit for restricted areas.

Response: The regulation does not set a limit on contamination in restricted areas. The licensee does that. The technician is then required to notify the Radiation Safety Officer if a limit for an area is exceeded.

Comment: The end-of-day survey section should require cleanup if removable contamination is found. Otherwise we can't issue a citation.

Response: Yes, you can. The survey section requires the surveyor to notify the Radiation Safety Officer if action levels are exceeded. One of the Radiation Safety Officer's duties is to "take emergency action in the event of loss of control" of material. Either restricted access to the area or cleanup are two appropriate actions. Doing nothing is not an appropriate action. The licensee would be cited for failure to take emergency action following loss of control of material.

## RADIOACTIVE GASES

Comment: Must the licensee initially open volatiles and radioactive gases in a fume hood?

Response: No. The licensee is required to store those materials in a fume hood or within a double container designed to prevent disbursement.

Comment: The Draft Regulatory Guide that you have prepared, in Appendix Q, refers to measuring xenon concentrations with a film badge. This is questionable as an acceptable monitoring procedure.

Response: The appendix talked about measuring worker dose from noble gas concentrations with a film badge. A recent manuscript suggested that some film badges are not capable of making satisfactory measurements. Therefore, the reference has been removed.

Comment: Are you no longer concerned with ventilation rates in xenon rooms?

Response: A new section has been added that requires calculations to establish room evacuation times for all rooms where gas is used or stored. The requirement is needed because normal room ventilation rates are usually not sufficient to ensure a timely clearance of leaked or spilled gas.

Comment: You should allow mobile services to carry multi-dose vials. The vials are just as safe to transport as unit dosage syringes.

Response: Done. A licensee pointed out that a unit dosage may be outside the desired prescription range if the mobile van arrives early or late. If the client had an extra patient, the van would not have a dosage on hand for the patient.

Comment: You proposed to allow mobile services to have licensed hospitals as clients. Is this a change in materials licensing policy? NRC usually doesn't allow this.

Response: The permission has been withdrawn from this draft. If an inspector were to find uncontrolled material, he would not be able to determine who was responsible for its loss.

Comment: You require that the mobile service consider the area of use at the client's facility to be an unrestricted area. If the area can't be controlled, the licensee shouldn't use the material.

Response: A full-time employee of the client such as a housekeeper or security guard may not be aware of the mobile service contract, and may be reluctant to follow safety instructions given by an outsider. Therefore, the mobile service must exercise greater control than that required of in-house nuclear medicine services. Thus the wording, "Client facilities should be considered as unrestricted areas." No change has been made.

Comment: The proposal requires that only the management of a client facility be allowed to request services from a mobile nuclear medicine service. However, service might be supplied if a physician at a client hospital requested service without his management's approval.

Response: This would only happen if the physician misrepresented himself as management, or if the mobile licensee ignored the regulation that requires him to have on hand an authorization letter from the client's management.

Comment: You should allow mobile services to use I-131 for treating hyperthyroidism, instead of restricting them to only diagnostic work.

Response: The drafting committee purposely omitted all radiopharmaceutical therapy procedures for mobile service licenses. If there is a need, it may be licensed on a case-by-case basis if accompanied by a license condition that exempts the licensee from Section 35.35 and also identifies the authorized therapeutic radiopharmaceuticals.

Comment: You should require that brachytherapy sources be manipulated with remote handling tools.

Response: No. The licensee is required to follow the safety and handling instructions supplied with the source and approved by NRC or an Agreement State. Not all brachytherapy sources need to be handled with a remote handling tool.

Comment: Brachytherapy sources aren't always promptly returned to storage. The licensee should count them at the time they are removed from the patient to be sure all of them have been removed.

Response: Such a requirement might be inferred to require counting them in the patient's room. It is not common practice to take a source out of one patient and immediately put it in another patient; given that, then wherever a source is taken to after removal becomes an area of storage, and a count must be made.

Comment: Why do you require licensees to survey once each quarter around brachytherapy storage areas?

Response: If the number of brachytherapy sources in the inventory increases, or if sources have not been properly stored, dose rates around the storage area may go over permissible limits.

Comment: Brachytherapy users also need a low range meter to make a quarterly storage area survey as required in the proposed Section 35.59(h).

Response: A low range survey meter is not appropriate for this kind of survey. The meter that the licensee must have on hand is needed to survey around each patient's room after the brachytherapy sources have been implanted.

Comment: Licensees should be required to survey with a low rage meter the area where low activity brachytherapy seeds are implanted in case they are lost in the surgical dressing.

Response: The survey is required, but the low range meter is not required. The lowest scale for most high range meters is either 0-1 or 0-3mR/hr. This is

sufficiently sensitive to survey the few square meters of space where sources might be lost.

Comment: Require both low- and high-level survey meters for teletherapy licensees. If the radioactive source gets stuck in the "on" position in a teletherapy unit, a GM survey meter may saturate or pin the indicator.

Response: No. For day-to-day use, a survey meter is needed only as a go/no go indicator in case the teletherapy room monitor fails. In case of a stuck source, the dose rate near the entrance will still be low enough to be measured with either kind of survey meter. Then, the next steps are to remove the patient and secure the room, not to measure the dose rates around the teletherapy unit.

Comment: You should require that technicians continuously observe teletherapy patients.

Response: No. Such a requirement appears to be unenforceable, and better mandated by the physician for purpose of patient care.

Comment: You should require that the licensee terminate teletherapy treatments if the patient viewing system breaks.

Response: No. The viewing system allows the technologist to monitor the patient's position with respect to the treatment beam so he can terminate the treatment if the patient moves. The decision on whether to interrupt patient care because of a broken viewing system is properly placed on the physician's shoulders. If a patient is cooperative, enforcing such a requirement may place the patient at a greater, not a lesser, risk because you would be denying him his cancer treatments.

Comment: A new teletherapy calibration procedure was recently published. You should require that licensees use the new procedure.

Response: The regulation has been revised to allow licensees to use the new calibration protocol to meet the regulatory requirement. However, not all licensees have the equipment needed to follow the new calibration protocol. Therefore, either is allowed.

Comment: You say that radiation "quantities" around new teletherapy units should be measured. Don't you mean "levels"?

Response: No. The word "level" connotes a continous or instantaneous rate. The regulation actually limits the total amount of radiation (millirems) that has been integrated over a period of time at a point. That concept is better characterized as a quantity.

Comment: Licensees should mount the teletherapy radiation monitor device so that it can be seen without entering the room. Otherwise, you have to be in the room with the teletherapy beam on to check the monitor.

Response: The monitor should be mounted so that you see it when you enter the room and therefore know if you are entering a safe or unsafe room. The monitor can be checked each morning with a hand-held check source in those cases in which it cannot be viewed either by a closed circuit television or through a viewing window.

Comment: Delete the authorization for drugs that have been approved by a Radioactive Drug Research Committee.

Response: Done. Further review has indicated that only a few licensees are currently authorized to use Radioactive Drug Research Committee authorizations. Applicants will be notified in the regulatory guide that they may be request specific authorization to use radiopharmaceuticals that have been reviewed and approved for medical use by an FDA-approved Radioactive Drug Research Committee.

Comment: Many of the listed radiopharmaceuticals are no longer used routinely. Therefore they should not be listed.

Response: Mercury-203 has been withdrawn because the radiation dose is much higher and the imaging quality much lower than for mercury-197. Otherwise, if the Food and Drug Administration has approved a radiopharmaceutical for safety and efficacy, and if the radiopharmaceutical is not hazardous to workers or the public, to not allow its use would be an unnecessary intrusion into the practice of medicine.

Comment: Since you also control suppliers, couldn't you just list permissible isotopes and type of use (i.e., "imaging"). Then, when a new pharmaceutical is developed, you would just have to amend the suppliers' package inserts.

Response: We have considered this. However, policy to date for all materials (not just medical use materials) has been to control both the distributor and the purchaser. We will continue to research the effects of the suggested change, but as a separate project. The purpose of the current project is to codify our current requirements.

Comment: Can a hospital supply other hospitals with materials without being licensed as a nuclear pharmacy?

Response: This is not the usual case. However, if the license reviewer believes the arrangement is safe and in the public interest, an exception from the authorized supplier requirement can be made.

## TRAINING AND EXPERIENCE

Comment: There is no assurance of adequacy of authorized users' training. Can NRC accredit sources of instruction or examine proposed authorized users?

Response: The problem is not unique to medical users, but rather applies to all industries under NRC jurisdiction. It should be settled as a separate policy issue, not as a minor issue in this proposed rulemaking. No changes have been made.

Comment: Can license reviewers approve new authorized users if their training meets Subpart J standards?

Response: Yes. The application instructions have been clarified.

Comment: Can physicians be authorized even though they don't meet the training and experience standards to "nth" degree?

Response: Yes. Exceptions are allowed pursuant to Section 35.29.

Comment: The 8 hours of training required of podiatrists is insufficient.

Response: For the one device they would be authorized to use, the amount of training appears to be sufficient. The 8-hour standard was developed in a separate project and was simply adopted here.

Comment: Only properly trained individuals should be allowed to transport materials.

Response: The Department of Transportation regulations apply to the transportation of byproduct material. No changes have been made.

Comment: Why do you want to list the radiation therapy physicist on the license? We don't do that now.

Response: In light of an incident a few years ago, in which several therapy misadministrations were precipitated by the physicist's inadequate training and

experience, it would be inconsistent to require identification of the authorized user and radiation safety officer on the license, but not the radiation therapy physicist.

## MISCELLANY

Comment: Because of the size and specificity of this proposal, a 120-day comment period is needed.

Response: Done.

Comment: You should clarify that persons who are now working under a general license authorized by Section 35.31, who you say will be exempt from fees in the future, will be restricted to the materials and uses allowed under Section 35.31 when they receive their specific license. If they want to use more material than is allowed by the general license, they should be required to pay application, amendment, renewal, and inspection fees just like everyone else.

Response: Done.

Comment: The current draft of the proposed Form NRC-313 is worded to indicate that the licensee may not change procedures without NRC approval. This conflicts with the Commission paper.

Response: The conflicting sentence on the form has been deleted.

Comment: You should provide more guidance for small research programs.

Response: No. Refer requestors to NRC Regulatory Guides 10.2, 10.5, and 10.7.

Comment: How much will it cost to convert in vitro general licenses to specific licenses? Currently, persons who hold a medical license are authorized, by the regulation, to also do in vitro work.

Response: Nothing. In vitro general licensees are unaffected by the revision. Human use licensees who are doing in vitro work under the provision of current Section 35.14(c) are grandfathered by a conforming amendment until renewal time. New and renewal applicants will have to request the in vitro materials as a separate single line item.

Comment: The February 1984 draft that was distributed for comment would allow the licensee to identify provisional authorized users (authorized users who have authorization already by virtue of being listed on another person's license), and allow them to work as authorized users until an amendment or renewal request

was submitted. A provisional authorized user might do procedures for which he has not been authorized, either by misunderstanding or intent, for several years instead of just for 60 days as permitted under the current visiting authorized user license condition. Several authorized users may come and go without notice to the regulatory agency.

Response: Ignorance of the law is not an acceptable excuse. If a physician can't understand limits on his scope of use, there is little assurance that he can understand the limits on its duration, whether he is called a provisional authorized user or a visiting authorized user. However, given the risk of loss of management control in situations where key users are regularly replaced, and given the unclear status of the occasional visiting user, who supervises use for one day, compared to the full-time user who should take an active part in the safety program, the 60 day limit has been reinstated.

Comment: In drafting a standard for release of patients who contain byproduct material, you have switched from the current requirement that patients who contain more than 30 millicuries not be released to a standard based on the dose rate at a distance from the patient. Do you mean that the dose rate at a distance is the only way to measure the residual activity in a patient who is about to be released?

Response: There are only a few ways to determine how much radioactivity is in a patient. Measuring of the amount of material that has been excreted and subtracting it from the amount administered may be more hazardous to the worker than other methods. Retention calculations are based on healthy standard man averages, not the pharmacokinetics of the ill individual patient. The dose rate measurement at a distance is meaningful, inexpensive, easy, and relevant. The licensee may select either the dose rate at a distance or the activity retained as his release standard. Other suggestions for patient release standards are welcome.

Comment: Changes in NRC regulations will affect Agreement State and NARM State programs.

Response: The NRC is aware of the fact that the effects of its policy sometimes go beyond its own jurisdiction. However, NRC also has a mandate from Congress that must be met with finite resources. Therefore, the probability of extramural effects cannot stay the NRC from doing its job as it sees best.

Comment: You should require that permanent implant patients be given radiation safety instructions before they leave the hospital.

Response: No. In the two instances where there is a clear hazard to the public and the patient's family members, permanent implant and radiopharmaceutical therapy, the regulation would not allow release of the patient above specified radiation levels. Below those levels, personal circumstances and needs of the patient and his family must be balanced against the radiation dose to the family and the public. The physician is best suited to determine what instructions should be given and to whom.

Comment: In the enforcement paragraph of the statement of considerations you discuss enforcement against an individual. You normally cite the licensee. Has policy changed?

Response: No. The paragraph said that licensees may be cited for several types of infraction. The closing sentence notes that if a person uses material and is neither named on a license nor working under supervision, then that person will be cited.

Comment: For diagnostic radiopharmaceuticals, will you limit the inventory amount to a specified number of millicuries, or continue to use the phrase "as needed" on the license.

Response: We will continue to allow inventories "as needed" for diagnostic radiopharmaceuticals.

Comment: You should delete incorrect dosage as a misadministration.

Response: It appears that the Commission wants to deal with misadministration as a separate issue. The current wording was purposely retained.

Comment: Why don't you allow decay of radioactive waste with a half life longer than 65 days, or decay for fewer than 10 half lives?

Response: The 65 day, 10 half-life limit appears to have met most of the licensees' needs. A sentence has been added to the statement of considerations

noting that the Commission will consider, on a case-by-case basis, applicants' requests for longer-lived material, or for a shorter decay period.