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November 27, 1985

Attention: Docketing and Service Branch

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

Subject: Comments on the Proposed Revision of 10 CFR 35

Sir:

Please accept my apologies for late submission of the enclosed comments. The job took much more time than I or my associates had anticipated.

Sincerely yours,

David E. Drum

David E. Drum, M.D.

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Sir:

During the past ten years I have been responsible for the administration of an institutional broad medical license. The following comments are based on that experience, an appreciation of the interrelationship of 10 CFR 35 with many other statutes, and professional concern that appropriate weighting of health care priorities, actual risks and known benefits be integrated into statutory regulation of medical practice.

I. General Notes:

1. The proposed consolidations and clarifications are perceived by most byproduct material users here as a welcome step toward efficiency.

2. The changes would appear of greater benefit to the NRC than to hospitals. The crossreferences for licensing and regulation have been more burdensome to you than to us; the changes will assign greater authority, hence responsibility and costs, to individual institutions.

3. Because revisions are also being made in at least two closely related documents, 10 CFR 20 and Regulatory Guide 10.8, I would recommend that all three be revised and resubmitted for comments simultaneously.

4. A substantial portion of the paperwork attending license applications and amendments has revolved around legitimate debate over interpretation of the statutes. I am not certain that the new changes will eliminate this, and it is possible that more recourse to the courts (or ill-will) could occur.

5. Institutional Radiation Safety Committees should be assigned the authority to name (and remove) authorized users without submitting license amendments for each new name as suggested by the proposed changes.

6. I believe the proposed regulations for "Misadministrations" are quite inappropriate and potentially harmful to the patients involved. These regulations should be deleted until a comprehensive reevaluation of the role of the Commission in this aspect of medical practice can be completed.

II. Specific Notes on the Discussion of the Regulations:

1. Page 30618, Paragraph 1, implies that Form NRC-313 will continue to be used. It would be helpful to revise this form, including only reference to 10 CFR 35.

2. License amendments (page 30619). Approval of new users, RSO changes, and qualified teletherapy calibration experts should be done by licensee's Radiation Safety Committee, guided by the new statutes. License amendments should not be required. Similarly, new types of use should be evaluated and approved locally, consistent with FDA regulations for IND, NDA and RDRC-type activities. Requests for using new materials should not have to go to both the FDA and NRC. Even new locations of use should require only notification, not license resubmission, provided that the corporate entity, management, and nature of work done is substantially unchanged. I would expect a condition of licensing to be that both competent management and the Radiation Safety Committee would ensure that statutory qualifications are always met - hence precluding these needs for amendments (and notifications, Section 35.18).

3. The definition and treatment of "authorized user" needs clarification (pages 30622, 30623). Surely the name of each user need not appear on the license (Sections 35.16 and 35.32). Each institution may have de facto many users authorized by the Radiation Safety Committee to use byproduct materials and direct the work of others (technologists or research assistants). The adjective "visiting" is unnecessary: either a user is authorized or is not (Section 35.34) "High level survey instrument" should be defined under the section on word usage.

4. Modify the term "management" (page 30623). I suspect few institutions have one individual responsible for "defining the licensee's policies and allocating personnel, budget, and space resources".

5. The concept of an ALARA program (page 30624) as a means for reducing collective radiation doses and ensuring procedural reviews has been judged by the Commission to be uniquely effective; has this been proven so for medical licensees? Aside from those using radiation producing machines, the exposures for most medical personnel are

either nonmeasurable or too small to engender any measurable hazard. The same may be suggested for effluent releases. Thus, I would raise for discussion the question whether any medical licensee should have an ALARA program. Most of our personnel with recurrent measurable exposures are of identifiable groups - such as nuclear medicine technologists; why not have a more selective, targeted evaluation of reasonable means for reducing their exposures - which are the only occupational exposures?

6. Radiation Safety Committee (Section 35.32), Column 3, Paragraph 3, line 4, should read "user of", not "user or". Again, I do not understand why each authorized user need be identified on the license. The need in the Committee is for broad expertise not necessarily representation explicitly by a physician of each user type. The section should specify that it is the Committee that should make the annual review of the safety program.

7. Mobile nuclear medicine services (Section 35.35) should be available to licensed clients if construction, accidents or strikes prevent normal delivery of diagnostic services to patients.

8. Program changes (Section 35.36). The details of this section are inconsistent with the goals of the proposed 10 CFR 35. Provided the regulations are adhered to, why should amendments be required for new methods (adhering to FDA regulations), new users, changes in quantity and kind of materials, and use location changes within a corporate entity? The decision criterion is whether regulations (e.g., 10 CFR 20) for exposures are adhered to by actions of the local Radiation Safety Committee (including special regulations for irradiators, teletherapy, etc.). The goal is to decentralize authority for changes. The major local changes that might impact discernible health and safety are changes in radiation therapy dosages to patients - generally not restrained at present by the Commission.

9. Misadministrations (Section 35.37). I am not certain that the present statutes for misadministrations are reasonable and effective, hence to make no changes is not desirable. Is it reasonable, for example, to require reporting of a diagnostic overadministration of 100 percent (e.g., 40 mCi instead of 20 mCi for a bone scan, delivering a dose-equivalent of about 1.6 rem instead of 0.8 rem) yet not require reporting of a therapy misadministration (overdosage) of 5% x 10,000 rads ≅ 50 rads! This is hardly in the public interest. If there is a certain radiation dose that is harmful, it should be reported to the licensee's legal department and executive medical committee regardless of whether the dose arose from diagnostic, therapeutic, occupational, or accidental sources or procedures.

The Commission should indeed concern itself with procedural or technical deficiences that lead to misadministrations. Whether the patient is to be informed should depend on local practice for other analogous medical misadventures. A number of qualitative and quantitative radiopharmaceutical "misadministrations" have insignificant/unmeasurable consequences; what is gained by way of safety or health if the patient and his lawyer are notified? What of the wide variations in "standard" dosages for radiopharmaceuticals?, e.g., 2 to 10 mCi for Tc-99m liver scans; 4 to 10 mCi for Gallium-67 scans; 2 mCi pertechnetate vs 30 µCi Iodine-131 for thyroid scans? Unless the Commission is prepared to specify dosages in the federal statutes, the new regulations for misadministrations should be rewritten to restrict its role to procedural aberrations such as noted above.

10. Supervision (Section 35.38). General guidance of employees is always to be desired. Special training elements such as nuclear medicine technology, radiation therapy technology, medical laboratory technology, or their equivalents are well established and should be respected. Research positions in medical institutions are less well defined but generally involve nonmeasurable exposures and small quantities of by-product materials. Thus, no changes are needed. If accident/exposure experience indicates a specific need for new regulations to supplement 10 CFR 20, they should be proposed.

Section 35.50, Dose Calibrators. I recommend the lower limit for linearity tests for dose calibrations be no less than 200 µCi, not 10 µCi. Many dose calibrators in common use are not designed/labeled for less than 200 µCi. Few diagnostic imaging doses are as low as 200 µCi; for in vivo tests that require less (e.g., I-125 iophthalamate or fibrinogen) either volume measurement or unit dosing can be employed with no significant harm to patients or employees.

Section 35.59, Page 30626, Paragraph 2, line 11, should read "finding", not "funding".

Section 35.70, Page 30627, Paragraph 1, line 4, should read "mislaid", not "misled".

Sections 35.315 and 35.415, Safety Precautions. A private room need not be required for radiopharmaceutical therapy. Today every empty hospital bed is a financial loss. Depending upon the geometric arrangement of a double room, for example, I can imagine that two patients could be given I-131 therapy simultaneously with adequate protection of the public. In institutions where many cancer patients

are treated, I could also envision radiopharmaceutical therapy given to one patient while a second ill patient recovers from external beam therapy. The local RSOs would assume responsibility for keeping exposures of the public consistent with 20.105(a) or (b).

Section 35.632, Page 30631, Paragraph 1, line 11, should read "unintentionally", not "unintentional".

III. Specific Comments on the Proposed Text, by Paragraph:

35.17(a) General methods and uses should be mentioned in the regulations, otherwise this requirement could be very restrictive.
(b)(c) Users should be authorized by the Radiation Safety Committee, not license amendments. Ditto for Radiation Safety Officers and qualified teletherapy experts.
(e) Location additions or changes for the same corporate entity and same management should not require formal license amendment.

35.32, Page 30638(2) should read "at least", not "a least".

35.37, Misadministrations. I do not believe misadministrations should be reported to the NRC, aside from entry of a report into the minutes of the Radiation Safety Committee. They should be evaluated individually and locally by the primary physician of record, the pertinent department head, the hospital's legal staff and the Radiation Safety Officer. Consider that the administered dosages for treatment of thyroid cancer vary from 30 to 500 mCi; it would be a matter of legitimate dispute whether 100 mCi represents a "misadministration" and, indeed, whether it will harm (or help!) the patient. I see no useful purpose to be served by a statutory requirement involving a patient in such disputes. Actual harm, of course, can be pursued by the usual legal means available to every citizen.

The same comments and rationale apply to diagnostic administrations. For thyroid imaging, what is the correct dosage, 2 mCi or 4 mCi of Tc-99m pertechnetate? For Gallium-67, 4 mCi or 10 mCi? There is no agreement, hence there cannot be misadministrations within an extremely wide (more than 50 percent) range.

35.38, Supervision. Paragraphs (3) and (4) are quite unrealistic. Rephrase to read, "the authorized user, an appropriate substitute or a representative of the Radiation Safety Office ....".

35.49. This section appears much too restrictive to stand as is. Many research uses, locally prepared reagents for in vitro testing, and IND/NDA/RDRC uses would be proscribed.

35.50. (3) 10 microcuries is much too small; I suggest 200 microcuries for the reasons explained above.

35.51. I believe 1000 mR/hr is much too high (and unnecessarily hazardous) for calibration of survey instruments used in hospitals. 100 mR/hr would be a more appropriate maximum. E n elution of 3 Curies from a Mo-99 generator, appropriately done does not engender exposure rates of 1000 mR/hr. Taken literally, (d) is much too restrictive for institutions possessing 50 or more survey meters used many times each day.

35.53. (a) Change 10 to 200 µCi, for the reasons above. Reemphasize: most dose calibrators do not go down to 10 µCi accurately.
(c)(3) Change to ".... less than 200 µCi".

35.59(f)(3) line 2, correct to "gamma-emitting".
(g). Inventory should be conducted every six months, consistent with leak testing in (b)(1).

35.70(f). This should read 10,000 DPM, to be consistent with 35.59(e), in medical institutions. 200 DPM is unreasonable and adds little to safety.
(h) Clarify to segregate exposure rate in mR/hr (not mrem/hr) from contamination counts in DPM.

35.80(a). Unnecessarily restrictive and costly.

35.100. This list needs modernizing.

35.120. How was the figure 1 mR/hr arrived at? For small quantities of isotopes as varied as I-125 and Fe-59, this is demanding for "a portable lower level radiation survey instrument".

35.205(d) and (e). Clarify what is meant by a spill. Is it all of a dosage of Xe-133? 10 percent? 1 percent? Is it instantaneous or slow/continuous?

35.310(b). What is the benefit from keeping a list of instructed individuals for two years?

35.315(a). A single room is not in all cases necessary or optimal, as discussed above.
(c) and (d). This information should be available, but it need not be a required part of the medical chart per se.

(f) This seems quite restrictive. Many survey meters may not detect 200 DPM per 100 cm^2. I recommend the figure be changed to 0.005 μCi per 100 cm^2 for consistency with other sections of 10 CFR 35.
(g) The benefit of this regulation is dubious at low administered doses, i.e., less than 15 mCi. I recommend that thyroid counting be done only for administrations over 30 mCi.

Subpart G. Why is there no mention of permanent implants for therapy, e.g., Au-198, I-125, etc? Also, what precautions are recommended for these patients in case of later surgery or other close work?

35.410(a). Instruction of all personnel about physical source details is inappropriate. Adequate written safety procedures should be available.
(b) Keeping records of those instructed seems unreasonable, as above.

35.415(a). A private room is desirable, but not necessarily always required. As written, this is too restrictive.

35.500. Isotopes such as Gd-153 should be added. Is Am-241 approved for use in fluorescence imaging of the thyroid?

35.621(b). Visible indicators of abnormal high radiation levels should be mounted on each of four walls.

35.641(a)(1). The geometric arrangement for these measurements should be specified more precisely (or reference made to regulatory guides, etc.).
(a)(2)(ii). This should read "limits specified in 20.105(a) or (b) ....".

35.643. Paragraph 1, line 5, should read 20.105(a) or (b).
(d). The text here should be made consistent with that above.

35.900(a)(1), line 2 should end with "or".
(a)(4). This should be inserted to read "American Board of Nuclear Medicine" to be consistent with 35.920.

These are rather restrictive requirements. I suspect there are many university related institutions wherein abundant expertise is readily available to a Radiation Safety Officer who is primarily a manager, not a user or board certified professional. Use of the "or" between paragraphs (a), (b), and (c) will surely encompass individuals of widely varying expertise.

35.910(3). This criterion should be deleted. In my experience most such individuals have had no training with unsealed radioactivity or with radiopharmaceuticals.

On the other hand, the very small dosages employed for the items listed in 35.100 (mostly microcurie quantities) engender minimal hazard to anyone. I recommend these be authorized users by way of the institutional Radiation Safety Committee, or, in small hospitals, have access to trained consultants and written procedures. As written, these educational requirements are unreasonably restrictive.

35.920(a)(1). Add "or" to the end of line 2.
(3) Delete. In my opinion, the typical diagnostic radiology training does not provide adequate instruction and experience for a professional who is to use and supervise use of the materials listed in 35.200.
(b) These requirements are highly restrictive and would be met by very few physicians. They should be written so as to be identical to those of the American Board of Nuclear Medicine.

35.930(2)(ii) and (iv). These are very rare usages today and should therefore be deleted. Perhaps a paragraph should include other applications (e.g., labeled monoclonal antibodies, intraarticular therapy with beta emitters, etc.).

35.940(a)(1). Certification by the American Board of Radiology alone is inadequate and dangerous.
(2) and (3) Should be deleted.

A paragraph explicitly describing training in <u>treatment planning</u> for both external beam and brachytherapy should be included.

35.941(a). Certification in radiology alone is inadequate and dangerous.

35.960(a)(1). Certification in radiology alone is inadequate and dangerous.

Many thanks for the opportunity to review this document.

Sincerely yours,

David E. Drum

David E. Drum, M.D.
Chairman
Radiation Safety Committee

DED:JBM