HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIATION THERAPY
DIVISION OF PHYSICS

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Medical and Academic Section
Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Walker:

I am responding on behalf of the New England Chapter of the American Association of Physicists in Medicine (AAPM) to the request for comments on the draft 10CFR Part 35. The New England Chapter is a 100 member regional unit of the AAPM which has a total membership of about 2000 physicists organized in part to promote the application of physics to medicine and biology. As individuals we are very involved with the licensing and use of radioactive materials in medical facilities and as an organization we are interested in participating in the development of any regulations regarding that use.

In general the proposed Part 35 is very clear and written in a manner that should be understandable to anyone involved in the human use of byproduct material. It is well organized and covers almost all aspects of that use. We do have a number of specific comments which I hope will be constructive and be considered as the final Part 35 is written. These comments are detailed below by page and paragraph number.

1. p6 para 35.15 It would be useful to include a definition of "Licensee". Under "Authorized user" it implies that physicians are licensed, but on p 7 it is stated that institutions can be licensed also. In the case of an institutional license, it is not clear how an "authorized user" is defined. Presumably each physician needs only to be named on the license, not also be licensed individually.

2. p9 para 35.30 The total radiation safety program referred to in this paragraph is more than an ALARA policy. Nowhere do you specify who is resposible for developing and implementing the radiation safety program. That responsibility should be addressed somewhere in Part 35.

3. p10 para 35.30 There should be a section covering ALARA for individual licensees who are not under institutions.

4. p10 para 35.30(d) Each user must also be responsible for compliance with the entire radiation safety program.

5. p10 para 35.31 It would read better if (b) came before (a).

6. p12 para 35.34(2) This seems to exclude the possibility of foreign visitors being considered visiting physicians. We have no objection if that is what is intended.

7. p12 para 35.34(3) The use of physician in this section is ambiguous. It is not clear whether the visiting physician in line 1 is the same person as the physician in line 2 or some one else.

8. p15 para 35.49 Qualified expert appears here without having been defined. Possibly a definition should be included in 35.15.

9. p15 para 35.50(a)(2) This section should specify that the test be made over the range of gamma ray energies which will be used, not just two different radionuclides, since the energy dependence of these calibrators is known to be significant over the range < 100 keV to Ra-226 energies.

10. p15-17 para 35.50,51 The requirements in these two sections should be parallel. Thus, for a dose calibrator:

    1. The maximum calibrated radionuclide dose under (a)(3) should be conspicuously noted on the instrument and a linearity correction chart, if needed, should be attached as required in 35.51(b)(2) and (c)(2).

    2. For the tests required in (a)(2) for the dose calibrator, records should be kept for the duration of use, not just 2 years (re: 35.51(e)) and they should include a description of the procedure and the source radionuclides used as well as the activity.

11. p17 para 35.53 There should be some requirements for the assay of pharmaceuticals which are pure beta emitters, such as P-32, used in therapy.

12. p18 para 35.59(a)(2) It is not clear what is meant by "test" in this context. Is this a leak test?

13. p20 para 35.70 This section should require:

    1. Specific surveys for airborne I-131 when administered orally in liquid form in therapeutic doses.

    2. Post-discharge surveys of patient rooms following any therapeutic use of sealed sources or pharmaceuticals.

    3. Surveys in areas where sealed sources are being used therapeutically.

14. p21 para 35.75 We suggest that you incorporate the guidelines contained in Table 4 of NCRP Report No. 37 which specify the activity depending on the radionuclide and its attendant hazards.

15. p21 para 35.90 Storage in a fume hood will not prevent an unintended release. It will simply assure that, should a release occur, the material will be exhausted to the outside rather than being released inside the building.

16. p26 para 35.204 Since there is a requirement to have the capability to identify 0.15 uCi of Mo-99 in 1 mCi of Tc-99m, there should be some specifications on instrumentation and calibrations for performing this measurement just as with calibrators and survey meters in 35.50,51.

17. p28 para 35.400 This list should also include Ir-192 as a wire.

18. p34 para 35.630(a)(2) If an intercomparison as detailed in this section is made every two years, there is no need for a calibration every four years. Thus, as in (a)(3), a calibrated dosimetry system is acceptable as long as intercomparisons are made every two years.

19. p35 para 35.630(a)(3) This section implies that the constancy check source must travel with the dosimeter to the calibration laboratory. An alternative which is equally acceptable is to test the dosimeter using the constancy check device immediately prior to sending the dosimeter to the calibration lab and check

it again immediately upon return from the calibration lab. If there has been no change in the results of the constancy check, one can assume a valid calibration.

20. The changes incorporated in 35.630 are a vast improvement over present calibration requirements.

On behalf of the New England Chapter of the AAPM, I express our appreciation for the opportunity to comment on this important revision.

Sincerely,

Kenneth R. Kase, Ph.D.

cc:J. Deye
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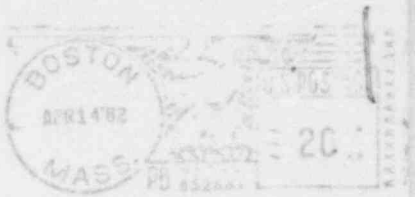

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