UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
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August 26, 1982

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

FROM: R. H. Engelken
Regional Administrator
Region V

SUBJECT: PROPOSED REVISION OF 10 CFR PART 35

We have reviewed the draft 10 CFR Part 35 transmitted by your memo dated August 17, 1982, and do not concur. While there are several areas where we are not in full agreement, this nonconcurrence is based primarily on Paragraph 35.51, "Calibration and check of survey instruments." This nonconcurrence is based on matters of safety and on matters of consistency with current and historical positions of the NRC on instrument calibration. Some specific areas of disagreement will be described.

We cannot agree with the 500 mr/hr cutoff point above which no instrument calibration is required or the position taken in the Statement of Considerations that dose rates above 500 mr/hr are not likely to be encountered in the medical environment. Hand exposures above 500 mr/hr would not be uncommon during loading and unloading or inserting certain brachytherapy applicators. One hundred millicuries of I-131 is not an uncommon dose in therapy. That quantity of I-131 results in a dose rate in excess of 1000 mr/hr at 4 inches. Dose rates above 500 mr/hr would be expected during emergency removal of a patient from a malfunctioning teletherapy device. Hand dose rates (surface) during elution of Tc-99 or during injection using an unshielded syringe routinely exceed 500 mr/hr. We believe instruments should measure and be calibrated at least up to 1000 mr/hr as presently recommended in NRC Reg. Guide 10.8.

From a safety standpoint, we believe it is important that all survey instruments used for dose rate or other quantitative measurements be calibrated on some regular defined frequency. We cannot agree with the position that GM devices are so simple and stable that calibration is required only on receipt and after repair. We doubt that you could get any technical or scientific organization (ANSI, HPS, AAPM, NCRP, NBS, etc) to agree with that position. It certainly does not reflect our experience with GM devices used by NRC inspectors in Region V. Most of our GM instruments are calibrated on a quarterly frequency, and it is not unusual for them to require adjustment at the time of that routine calibration. GM type instruments are the only available instrument in many medical programs, and they should be calibrated at least annually if they are used for dose rate or other quantitative measurements. This has been the Region V position on earlier comments, and we continue to maintain that position.

We recognize that some added confidence in instrument results would be achieved by use of the dedicated check source before and after each instrument use. However, that process also has serious limitations. It would be a single point check on one range only. Because of personnel exposure problems, the source undoubtedly would be small, resulting in a check on one of the lower ranges, below the level of real interest. Also, many GM type instruments utilize internal detectors on the higher ranges. Such a source check would not even test those circuts for operability, much less accuracy.

This position on exemption of GM instruments from routine calibration requirements is not consistent with any position that NRC has taken in the past. It also is in disagreement with present NRC policy in all other parts of the nuclear industry. We do not understand or agree with this position and cannot concur. NUREG-0593 shows that the medical licensees are exceeded only by light water power reactors in total man-rem collective occupational dose, and are high up on the list of all categories of byproduct material licensees in average individual occupational dose. Therefore this exemption cannot be justified on the basis of limited low exposures.

As a footnote, we call your attention to the fact that the present proposed wording would exempt instruments other than GM type from calibration. Thus scintillation, and possibly other types of instruments would be exempt. Only ionization chamber instruments would be calibrated on a routine basis.

In summary, we believe instruments should be calibrated up to 1000 mr/hr, and all instruments used for dose rate or other quantitative measurements should be calibrated, at least on an annual basis.

This new draft of the proposed revision of 10 CFR Part 35 contains a great deal of new text in the Statement of Consideration which we have not seen before. We believe one position stated therein deserves comment. On Page 19, reference is made to 30.18 and on Page 22 reference is made to 30.71. In both locations the references infer that small quantities of radioactive material are under some sort of a blanket exemption from licensing requirements. That is not the case. As you know, the exemptions authorized by 30.18, the exempt concentrations listed in 30.70 and the exempt quantities listed in 30.71 apply only in very limited specific circumstances, and do not apply to the two situations discussed on Pages 19 and 22 of the draft. We believe the inclusion of those references is confusing and misleading, and would perpetuate the misunderstanding that many have of the exemptions authorized by 10 CFR 30.18. We recommend that those references to Part 30 on Pages 19 and 22 be deleted.

R. H. Engelken
Regional Administrator

cc: Regional Administrators
RI, RII, RIII, RIV
L. I, Cobb, IE:HQ