DEPARTMENT FOR HUMAN RESOURCES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621

BUREAU FOR HEALTH SERVICES

May 28, 1982

Lloyd Bolling
U.S. Nuclear Regulatory Commission
Office of State Programs
Washington, D.C. 20555

Dear Mr. Bolling:

After review of the draft proposed revision to Part 35 on Human Uses of Byproduct Materials, the following comments are offered:

1. Would NRC applicants have to submit for review their formal medical ALARA program or would the NRC applicant just indicate an ALARA program per the regulation 35.30 would be implemented? In addition will the applicant have to indicate an "exposure action level" associated with their ALARA program and submit such to the NRC prior to obtaining a license?

2. It is my understanding that the misadministration reporting requirement is being done away with. Such requirement is still in the proposed change to Part 35.

3. Concerning Xe-133 usage, is a stated value for the MPC of Xe-133 at the point of release sufficient to evaluate the situation when the methods used by the applicant for determining this value are not necessarily known in that such methods were not submitted for review (items 21 and 22 of the proposed application)? In addition, items such as dispensing and collection or trapping of the Xenon do not appear to have to be addressed by the applicant in his submittal to the NRC.

4. If an applicant does not wish to adopt a particular procedure listed in the revised RG 10.8, does the applicant just develop a procedure on their own and put it into use without having to submit this alternative procedure to NRC for review?

Assuming the answer is "yes", how will the NRC handle a situation in which the licensee is cited by a NRC inspector for using a procedure which did not meet NRC regulations? Would the licensee have to submit a revised procedure in writing to the NRC for review in order to eliminate the non-compliance item or would the licensee just have to check a box on a form indicating he would revise his procedure to comply with NRC regulations in order to eliminate the non-compliance item?

5. Will the general medical licensees who are to become standard medical licensees be required to adhere to Part 20 and/or Part 35 concerning waste disposal? It is my understanding that currently NRC general medical licensees are not required to adhere to Part 20 and that these licensees discard test tubes contaminated with I-125 without regard to radioactivity. If the general licensee who becomes a standard medical licensee is required to adhere to Part 20 and/or Part 35 will the licensee have to hold such material based on a decay to background philosophy and associated regulations or will the NRC consider an exempt concentration level as for H-3 and C-14 liquid scintillation media. Such I-125 exempt concentration level has been considered by Louisiana and Kentucky.

6. How will the NRC initial inspection frequency of medical licensees be altered by this proposed change in licensing procedure?

7. Such proposed licensing change will place quite a shock to a physician who, if once licensed by the NRC, wishes to obtain a license from an Agreement State which has not adopted such NRC philosophy.

8. Can we expect similar changes in other areas of NRC licensing such as in radiography, well logging, Broad Medical/Academic, etc.? I assume NRC licensing practices for reactors are not going to include such a system in which the applicant checks a box on a form indicating the utility will follow the appropriate regulations.

These comments are being submitted to you by the June 9, 1982 deadline indicated in the transmittal memo. Further comments may follow if we feel it is appropriate.

Sincerely,

Roy P. Osborne, Supervisor
Registration, Licensing and
Certification Unit
Radiation Control Section
Radiation and Product Safety Branch

RPO:smb

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Secretary of the Commission
Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

Dear Sir:

The NRC publication of a petition for rulemaking from the American Association of Physicists in Medicine (FEDERAL REGISTER Docket No. PRM-35-2) was reviewed by several scientists at the Bureau of Radiological Health (BRH) of the Food and Drug Administration (FDA). We have particular interest in this suggested change in dosimetry system calibration intervals because, while the NRC has regulatory control of radionuclide teletherapy units, our agency has specific mandates to provide reasonable assurance of the safe and effective performance of medical devices for both radionuclide and electronic product teletherapy units used in radiation therapy, including low-energy x-ray and accelerator units. It stands to reason that a treatment facility having both radionuclide and electronic product teletherapy units and only one dosimetry system would not wish to be required to calibrate that system at various differing intervals to satisfy two federal agencies and perhaps a State agency with its own regulations as well. The existence of various requirements could lead to possible inconvenience of a medical facility being without a dosimetry system for unacceptably frequent periods of time and to unnecessary calibration expense. Consequently, we urge NRC to consider this important aspect as it evaluates the possibility of changing its calibration requirements.

We have several specific comments regarding the petition. First, the word "teletherapy" used in the AAPM petition is generic and means "therapy at or from a distance," thus it includes therapy by radiation from electronic products as well as from radionuclides. Since the AAPM is petitioning NRC which only regulates radionuclide (byproduct material) teletherapy, some term indicating this limitation should always be associated with the word "teletherapy" in the petition and in NRC regulations; e.g., cobalt-60 teletherapy.

BRH agrees that is is very difficult for NBS and the three Regional Calibration Laboratories (RCL) to keep up with the NRC requirement, which became effective July 29, 1979, that dosimetry systems be calibrated every two years. We are quite interested in working with NRC to develop a solution which satisfies all the public health aspects of this serious problem.

An AAPM survey by Larry Lanzl in 1979 showed there were about 1100 instruments needing this calibration, and a Patterns of Care Study Facilities Survey in 1980 showed that just under 50 percent of the megavoltage teletherapy units were cobalt-60 (over 50 percent were accelerators.) It could therefore be deduced that as many as 550 dosimetry systems need calibration under NRC regulations, or about 275 per year under current requirements.

The AAPM reference by Shalek, et al. states calibration rates as follows:

FACILITY	CALIBRATION CAPACITY - NUMBER/YR (7/78 - 6/79)
NBS	less than 100
MDA-RCL	102
MSK-RCL	65
VIC-RCL	75
Total	up to: 342

This capacity would be enough to cover the instruments used to calibrate cobalt-60 teletherapy units, but not those additional instruments that might be used for linear accelerators only (about 275 more per year under similar requirements). Further, the Victoreen RCL is slated to close in June 1982, thus reducing the above total to 267. If the number of field instruments referenced by Shalek, et al. is taken as a minimum of 1057 (including those used for accelerators only) and is divided by four (under the petition for a four year frequency), the result is 264 instruments requiring calibration per year. This is just slightly less than the 267 projected. Since AAPM requested an extension from two to four years before they knew Victoreen was closing its RCL, their proposal becomes a marginal solution. The AAPM accredits the RCL's and has recommended the accreditation of a fourth RCL (Lanzl's report), but soon there will be only two. If any of the remaining facilities should lower their capacity or drop out, even this AAPM proposal would become obsolete. And at present, there does not seem to be any incentives for new RCL's to start up.

The AAPM proposal does have certain significant merits. The requirement of constancy checks with a small shielded radioactive source and a mid-point intercalibration are excellent quality assurance measures and should be considered even if the required calibration interval remains at two years. However, protocols for constancy checks and intercomparisons must be developed. Agreement must be reached with NCI, supporter of the RPC and CRP's, and with the AAPM regional chapters to carry out the required intercomparisons at frequencies necessary to make the intercomparison available to all users at the proposed time interval.

Conceptually, the AAPM proposal is based upon the proposition that a four-year calibration cycle (albeit with constancy checks and intercomparisons) is satisfactory for assuring accurate therapeutic doses. However, we are unconvinced that the evidence presented in the reference by Shalek, et al. contains sufficient data to support the conclusion that a four-year cycle for calibration is the most appropriate one. The data he submitted are limited to institutions visited by the Radiological Physics Center. These institutions are taking part in protocols sponsored by the National Cancer Institute and as such are not necessarily representative of all therapy institutions within the U.S. We do not have data to disprove Shalek's conclusions, but we believe that further study regarding the appropriate frequency of dosimetry instrumentation calibration needs to be made before such a drastic change should be approved.

The ultimate solution to the calibration capacity problem may be to improve the directly traceable calibration system, even if four years is the correct interval. Perhaps four RCL's could be established with NBS supplying calibrations only to them. The RCL's could then charge the appropriate fee to make the service at least self-sustaining, if not profitable. This might even encourage the entry of additional RCL's into the marketplace.

I would like to emphasize that a decision by NRC to change the required calibration frequency may run counter to a number of extant regulations and recommendations affecting both NRC licensees and other users. The Suggested State Regulations for the Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors (CRCPD) and the AAPM "Code of Practice for X-Ray Therapy Linear Accelerators" each recommend calibration every two years for dosimetry systems used to calibrate medical linear accelerators. At this time the "Code of Practice" remains the standard for accelerator operation in radiation therapy. Also, the Task Group 24 of the AAPM Radiation Therapy Committee is preparing a recommendation on Physical Aspects of Quality Assurance in Radiation Therapy. The most recent draft is recommending a constancy check of linear accelerator teletherapy photon output more than once a week. Many of the Task Group members would recommend daily checks. NRC requires a spot check of cobalt-60 teletherapy output once a month. There may indeed be different needs for the calibration of dosimetry instrumentation used for electronic product teletherapy than those used for cobalt-60 teletherapy. But, we suggest that NRC coordinate a review of the evidence and any changes to be made in the calibration frequency of dosimetry instrumentation with the other affected agencies. This should include at least the National Bureau of Standards (NBS), the BRH and the State programs, possibly through the CRCPD. At a later time the clinical community, both physicists and physicians, could be invited to make input. We agencies with relevant authorities can, by coordinating our requirements and programs, make an immeasurable contribution toward the betterment of radiotherapeutic care of patients. We should do no less.

Sincerely yours,

John C. Villforth
Director
Bureau of Radiological Health