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MEDICAL COLLEGE OF WISCONSIN

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PROPOSED RULE PR 20, 32+35
(63FR43516)

Attention: Rule Makings and Adjudications Staff

Dear Sir:

This letter contains comments on the review of the proposed revision of Part 35, focusing on brachytherapy. In several places the draft document, e.g. 35.600, the sealed source and device registry is mentioned. This particular registry is unknown to me. The proposed revision would be strengthened if there were an indication as to the nature of this registry and how to obtain a the copy.

The details of the written directive are presented in paragraphs 35.40 and 35.41. It is my opinion, based on numerous discussions as a result of NRC inspections, that substantial time is wasted in discussions relative to whether a specific approach by the institution meets the exact requirements found in Part 35. It is my suggestion that the NRC revise these paragraphs to the extent that while they require the licensee to have a written directive which specifies the essential elements of the procedure, the regulation no longer define the individual elements. If the written directive is really meant to be a tool to communicate between the authorized user and their support staff, then there should be substantial flexibility in its limitation. The institution should define the essential elements of the procedure, not the regulations. For example, the paragraph requires the inclusion of the total dose for remote afterloading. The number of fractions and the dose per fraction are required and thus, by easy mathematics, the total dose. My concern is that the written directive may lead to confusion in a medical event if two different doses are required on the written directive.

In paragraph 34.41(b)(3) I would recommend adding the "/or" after the word "and" to acknowledge that either manual or computer generated dose calculations.

In paragraph 35.4910CFR Part 30 is referenced. I do not know if Ir-192 seeds and ribbons which are not a sealed source, are included.

Paragraph 35.62 would require my institution to obtain dose calibrator for the 4 –8 Sr-89 therapies which we perform each year if we did not use unit doses. I believe

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that this is a reasonable development. It is my opinion that each institution has responsibility to determine the radiation dose or the activity to be delivered to their patients. I do not know if there is an NIST traceable source for Sr-89. Currently, we are trusting the vendor.

Paragraph 35.415(b)(4) requires supplies necessary to surgically remove applicators and sources from a patient. It is my opinion that this requirement is too vague to be reviewed during the inspection process. It is not clear to me what supplies should be where either about the multiple rooms we use for brachytherapy.

Paragraph 35.633 is devoted to full calibration measurements on remote afterloaders. Unfortunately, there is no reference to paragraph 35.630, which describes dosimetry equipment. I would recommend referencing paragraph 35.630.

Paragraph 35.643 discusses spot checks at the beginning and end of each week and at the beginning of each day. I am favor of eliminating the requirements for the beginning of each week and incorporating them into each day of use. The time required to verify source position, determine the source strength and to compare with the decayed value is very small and should impose a hardship on users. These parameters are very important to insure patient safety.

Paragraph 35.657 relates to therapy computer systems. It is my opinion that this paragraph is not very useful. Great efforts are made to ensure that planning systems are "operating appropriately". However, I do not know any method to guarantee that software "shall" always operate appropriately, despite substantial time and effort. Operating systems for computers are very complicated software packages. As the current Y2K issues indicate it is difficult to know if an operating system is "operating appropriately". It is also noted that there is no reference to new versions of planning or operating systems software. New software versions require extensive testing.

Paragraph 35.432 discusses full calibration measurements of brachytherapy sources. The purpose of the word "full" is not clear. It is my opinion that the requirement for each institution to calibrate brachytherapy sources is reasonable and is consistent with AAPM TG40 recommendations. For the last decade plus at my institution, we have calibrated every source or a sample of sources which have been used for brachytherapy. It is my belief that the institution is responsible for the dose delivered to the patient and the appropriate calibration of the source is part of confirming the dose delivery. This is consistent with one as standard of

practice for external beam therapy. We have a calibration system traceable to the NIST for I-125 seeds, Cs-137 sources, and Ir-192 seeds. The requirements of (C)(2) are simply NOT possible for prostate implants in which seeds are loaded in needles under sterile conditions at the time of the procedure. The definition of applicator is not clear, nor is it included in paragraph 35.2. A list of the applicators would be helpful.

Paragraph 35.3045 uses the phrase "reasonably prevented by the licensee". The judgment as to what is reasonably prevented is clearly a medical judgment. This version of the regulations will most likely lead to extensive legal discussions between the licensee and the NRC. It is my opinion that any patient intervention should not result in a medical event.

Thank you for the opportunity to comment on these draft regulations.

Best wishes,

Michael T. Gillin, Ph. D.
Professor

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