72

May 10, 1990

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

Attention: Docketing and Service Branch

Dear Sir:

Following up on our request for a 30 day extension on the April 12, 1990 deadline comments to NRC 10 CFR Part 35, RIN 3150-AC65, we offer the following comments.

We are in full support of the spirit of the document. It is a significant improvement over the prior document and we believe, as you do, that quality assurance programs will result in an overall improvement of the quality of care in therapy facilities in this country.

Our major disagreement with the document stems from its proposed enforcement, especially with regard to reporting errors. As we understand it, the radiation safety officer will be designated to enforce this program. In our large institution, where we have had a rigorous quality assurance program in place, we identify deviations from our quality assurance standards each month. Almost without exception, they are random human errors, and not systematic ones. They are identified, analyzed and understood. Since these are predominately random errors, they do not recur. If federal, state, or city laws require, they are reported. Thus, our experience would render inappropriate the statement on page 1445, V "Enforcement", the Commission "views the occurrence of ... reportable events as evidence of inadequate quality assurance". Quite the contrary, the identification of reportable events document excellent monitoring of a therapy facility, provided that the frequency of such is reasonable. It may be that facilities which never or rarely report errors are not adequately enforcing their quality assurance program, and therefore are not finding their errors. We suggest rewording the document so as not to associate "good quality assurance" with no reported errors and inadequate quality assurance with the occurrence of reportable events.

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We also offer he following specific comments:

Brachytherapy

35.34 (b)(4). We support the specifiation to a ± 20% as the acceptable error for reportable error-caused dose variation for brachytherapy. Although single-source dosimetry for currently used sources is now better than ± 20%, there may be valid arguments that actual minimum dose delivered to the target volume is uncertain by more than that amount in many instances. Our feeling, however, is that ± 20% is a reasonable level at which to require a review of procedures and, by extension, a reasonable level for reporting to NRC. Telling the patient, when the variation is close to the level of uncertainty or to the level of "normal" variability, is a separate issue that must be considered for radiotherapy in general. In the case of permanent implants of ^{125}I seeds, when no error is made and the nominally intended "matched peripheral dose" is 16,000 cGy, the usual variation (one standard deviation) in the evaluated matched peripheral dose is about ± 25%, a variation attributable to difficulties in seed placement, departure of target-volume shape from the ellipsoid assumed by the evaluation method, etc.

DG-8001 C.4. These elements of a brachytherapy QA program were obviously not intended to apply to remote afterloading. It is probably better to postpone recommending a QA program for remote afterloaders until standards currently being developed by the AAPM and other organizations have been published. In this guide, there should be a mention at the beginning of C.4 that the specific elements do not apply to remote afterloading. Otherwise, inconsistencies would arise as illustrated by the following examples. For example, in Section 4.5, radiographs of the applicators or catheters with dummy sources are usually taken before the sources are introduced, rather than after (also true for temporary implants not involving remote afterloading),. Also, since high-dose-rate remote afterloading involves treatments of only a few minutes, the requirement in section 4.8 for a check before 50% of the dose has been delivered is not applicable. Also, with respect to 4.6, planning methodology for newer modalities of brachytherapy is often developmental, especially at larger institutions. Examples are percutaneous perineal implants and stereotaxic brain implants. For these modalities, it is often true that all persons knowledgeable about planning methods are actually involved in the planning. In that circumstance, there is no one available to perform the independent check, and the best that can be achieved is that the radiation oncologist evaluates the plan (or the post-implant dose calculations) for plausibility as well as suitability.

External Beam Therapy

35.34 (b)(3)(iii) "For the fractions administered to date, the sum of the administered fractional doses differs from the sum of the prescribed fractional doses by more than 10% of the prescribed

total dose, i.e. the prescribed dose for all fractions not just the fractions administered to date". We believe this misadministration definition adds no useful refinements for quality assurance than those already contained in the other two definitions of misadministrations, i.e. sections 35.34 (b)(3)(ii) and 35.34 (b)(3)(i). As an example, a commonly prescribed dose schema for metastatic bone disease is 400 cGy X 5, for a total dose of 2000 cGy. If a patient received 2 fractions of 200 cGy per fraction, rather than the prescribed 400 cGy per fraction, the sum of the doses after these 2 fractions would be 400 cGy, rather than the 800 cGy intended by the physician. This is a difference of 400 cGy, greater than 10% of the total intended dose of 2000 cGy. Using this definition of a misadministration, this event would be reportable, although the patient would suffer no risk for any increased complications and would be receiving adequate palliation with the 200 cGy per fraction doses. A change in the prescription at that point would still ensure excellent outcome in terms of palliating the symptoms from the tumor with no increase in the risk of side effects to the patient, provided additional fractions were added. Yet this is a definition of a major misadministration.

Misadministration Reporting

Reporting events and misadministrations to the NRC, the state or the city involved is an important part of quality assurance. However, 35.34 (d), requiring the licensee to notify the referring physician and the affected patient of any misadministration defined above is dose oriented, rather than patient oriented. The delivery of a lower dose than that prescribed, especially for only a single fraction, will never result in an increased risk to the patient in terms of complications, nor the need for medical care implied in this section. In our judgment, notification of the patient in this case would only result in unnecessary worry on his or her part. We believe a re-wording of this section to require immediate notification of the patient if he or she is at risk for a radiation complication or sickness, in need of immediate care related to the misadministration or if tumor control in the judgment of the physician as been compromised is appropriate, but notification of the patient for a misadministration which will in no way affect tumor outcome nor normal tissue tolerance should not be required.

Sincerely yours,
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