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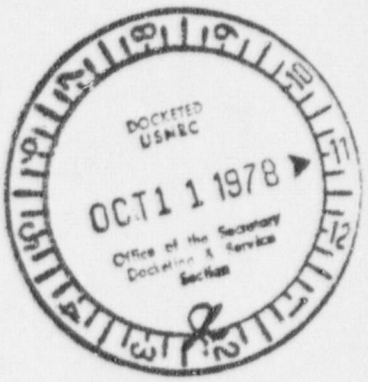

Mr. Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Chilk:

I am writing with regard to the Proposed Rule published in the Federal Register, Vol. 43, No. 131 - Friday July 7, 1978.

I would like to register my opposition particularly to the radiotherapy aspects of the proposed "misadministration" rule. Although the aims may be well directed, the methods proposed do not appear to result in any direct or long-term benefit to the patient other than to provide a basis for a malpractice suit. Such reporting might well result in a negative psychological reaction and in a lack of confidence in the physicians whether justified or not. If real harm is done, which cannot be corrected by proper medical care, then the malpractice approach is available to the patient.

From the technical aspects of radiation therapy, there are a number of problems which would have to be considered if this rule is adopted. During a course of radiation therapy treatment plans may change, for example tumor response, patient reaction, side effects or a revaluation might result in a change in the planned dose or exposure. If an error were discovered that a lower dose was delivered than prescribed, then suitable corrective action probably would be feasible. If a higher than prescribed dose were delivered then appropriate clinical action would be required to minimize adverse effects. Informing the patient, the referring physician, and the NRC would interfere with the normal patient-physician relationships and would not improve the treatment.

In the preparation of teletherapy treatment plans, dosage variations greater than 10% are common within the treatment volume. Some radiotherapists plan different doses within the tumor both for reasons of tumor response and protection of radiosensitive structures within the treatment volume. In treatment planning time-dose relationships, normal tissue sensitivity, and relative biological effects must be considered. A different total dose number for the same effective biological dose may result with any change in the treatment plan. Radiological inhomogeneties are included in dosage calculations by some centers but not by others. The numerical values obtained for a given treatment plan may vary markedly dependent on the inclusion or not of these inhomogeneity corrections. In brachytherapy, due to the geometrical positioning of finite sources, large dosage variations within the tumor volume are normal. A lawyer in a malpractice suit probably would have no difficulty in showing that a dose within the treatment volume differed by more than 10% from the prescribed dose.

In therapy it is reasonable that records should be kept of radiation source calibrations as well as complete treatment records including films related to the treatment. In addition, in brachytherapy a record of source counts and patient monitoring before discharge is reasonable.

To prevent recurrence of a misadministration caused by equipment malfunction, which might occur again or with other units, then a report to the NRC, BRH, equipment manufacturer and users would be appropriate. Operational and calculational errors may be minimized by employment of well trained personnel who work accurately with attention to details and the complete picture. Establishment of careful procedural methods within a therapy center which include provision for checks of patient set-up, treatment planning and calculations would also help minimize misadministration of dose.

To comply effectively with the intent of the proposed rule, it would be necessary to monitor the daily and/or total dose delivered to the patient. This would entail in vivo dosimetric techniques and would not be feasible in many cases.

I appreciate the opportunity to comment on the proposed misadministration rule and believe that it would not improve patient treatment or achieve the goals of the Nuclear Regulatory Commission.

Sincerely yours,

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