UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

SEP 8 1986

V. Miller -
Prepare response for REC signature (discuss with him if necessary)
L. Rouse 9/5/86

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

FROM: Frederick J. Hebdon, Deputy Director
Office for Analysis and Evaluation
of Operational Data

SUBJECT: UPDATE ON NMSS ACTION IN REGARD TO RECOMMENDATIONS MADE IN AEOD CASE STUDY REPORT: "THERAPY MISADMINISTRATIONS REPORTED TO NRC PURSUANT TO 10 CFR 35.42," AEOD/C505

While AEOD publishes an annual update of the status of AEOD recommendations contained in our case study reports, we review the status of these recommendations semiannually. In this regard, we are in the process of reviewing the status of the three recommendations contained in the subject report directed to NMSS (Recommendations 1, 2, and 3 - see attachment 1). Our review shows the following:

Recommendation 1: No action

Recommendation 2: To be addressed as part of rulemaking concerning verifying accuracy of therapy doses directed by the Commission. (Addressed in a memorandum from Richard E. Cunningham, NMSS, to Frederick J. Hebdon, AEOD, dated May 30, 1986.)

Recommendation 3: To be addressed as part of rulemaking concerning verifying accuracy of therapy doses directed by the Commission. (Addressed in a memorandum from Richard E. Cunningham, NMSS, to Frederick J. Hebdon, AEOD, dated May 30, 1986.)

To date, we are not aware of what specific action is being taken to implement Recommendation 1. While we consider all of the recommendations important, we consider Recommendation 1 especially important in that we feel, as a minimal effort in response to the findings of the case study report, licensees involved with radiation therapy should be apprised of the information contained in the report. We note that you share our concern by your comment on the preliminary case study report: "We believe that the information in the case study report is important and should be shared as soon as possible with the radiation therapy community."

Please inform us of the actions to be taken to implement Recommendation 1 and the date at which you expect the actions to be completed.

If we can be of further assistance please let us know.

Frederick J. Hebdon

Frederick J. Hebdon, Deputy Director
Office for Analysis and Evaluation
of Operational Data

Attachment:
As Stated

Attachment 1

RECOMMENDATIONS

(1) AEOD recommends that the Office of Nuclear Material Safety and Safeguards (NMSS) should communicate the information contained in this report to the affected licensees.

(2) AEOD recommends that the Office of Nuclear Material Safety and Safeguards (NMSS) should consider the following actions in regard to establishing quality assurance requirements for radiotherapy facilities* licensed by NRC.

-- Contact appropriate professional organizations to encourage and support the initiation of a voluntary, industry-directed physical quality assurance program for radiotherapy facilities. We believe that the commitment of the professional organizations in this regard should be assessed by the NRC and a conclusion reached as to the effectiveness of the voluntary program within two years.

-- If substantial progress toward completion of the voluntary program, including a final completion date, has not been demonstrated at the end of two years, we recommend that NMSS initiate the necessary studies to determine whether a rulemaking is justified to require that radiotherapy facilities licensed by NRC have quality assurance programs to insure the accuracy of patient doses. The program should include such things as: independent verification of patient dose calculations and independent verification of the activity of brachytherapy sources before the sources are implanted.

-- The voluntary quality assurance program should contain at least the elements outlined above.

(3) 10 CFR Part 35.21 should be amended to include the calibration of beam modifiers such as wedge filters, shaping filters, trays, etc.

(4) In addition, to the extent that the NRC implements Recommendation 3, the action should be made an item of compatibility for Agreement States.

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*A comprehensive quality assurance program in radiation therapy has both a clinical component and a physical component. The clinical component includes such things as clinical evaluation of the patient, therapeutic decision (e.g., curative, or palliative treatment, and choice of treatment modalities). The physical component includes such things as dosimetry, treatment planning, treatment machines and simulators, and radiation safety.