

13-15734-01



INDIANA UNIVERSITY

OFFICE OF THE DEAN  
Fesler Hall 302  
1120 South Drive  
Indiana University Medical Center  
Indianapolis, Indiana 46223  
(317) 274-8157

SCHOOL OF MEDICINE

May 17, 1989

Bruce S. Mallett, Ph.D., Chief  
Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission - Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Dear Dr. Mallett:

The purpose of this correspondence is in reply to two separate letters from your office. One of those letters was a "Confirmatory Action Letter" dated April 26, 1989 from Mr. A. Bert Davis and the other was a "Notice of Violation" letter from yourself dated May 8, 1989. In reply to the Notice of Violation, the following actions have been implemented:

1. A copy of 10 CFR 35.33 has been circulated to all members of the Radiation Oncology staff. Upon review, each staff member has signed a form documenting that they have reviewed this portion of the regulations. A copy of those signatures will be kept on file in the Radiation Safety Office for review by NRC inspectors.
2. To prevent future violations of this nature, the following additional procedures have been (or will be) implemented:
  - a. A synopsis of the requirements in 10 CFR 35.33 is now included in the Radiation Therapy Technologist (RTT) Manual. This manual is provided to each newly hired RTT and is also available at the console of each therapy machine.
  - b. New Radiation Oncology residents will be provided training regarding the requirements of 10 CFR 35.33 as well as other applicable regulations and procedures. Documentation of this training will be maintained within the Radiation Safety Office.
  - c. A synopsis of the requirements in 10 CFR 35.33 is now posted in the Radiation Oncology Department in an area frequented by the Radiation Oncology staff. This posting will be updated as necessary by the Radiation Safety Staff.
3. Full compliance has been achieved as of the date of this correspondence.

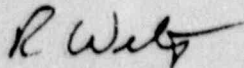
8906130215 3pp

MAY 24 1989 A1237

Bruce Mallett, Ph.D.  
May 17, 1989  
Page 2

In response to the "Confirmatory Action Letter", a copy of the Radiation Oncology Department's Quality Assurance/Quality Control (QA/QC) procedure for external beam radiation therapy is attached. We trust that the aforementioned information satisfies the requirements of your two previous letters. We are confident that the actions we have taken will prevent future problems of this nature. Should you have any questions, please do not hesitate to contact me. Thank you for your assistance in this matter.

Sincerely,



Mr. Robert Welty  
Assistant to the Dean

Attachments: 1

cc: A. Davis, NRC Regional Administrator  
W. Daly, M.D., Chairman - RSC  
J. Lindemann, M.D., Chairman - RRSC  
M. Richard, M.S., RSO  
D. Uhl, Hospital Administration

QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES  
FOR ADMINISTRATION OF EXTERNAL BEAM RADIATION THERAPY

1. The simulator technologist shall read the physician's written description of the anatomical area to be treated (as documented on the prescription sheet) before starting to simulate the patient.
2. Each prescription entry shall be initialed and dated by the physician making the entry. If the physician is not a staff physician (e.g. a resident), a staff physician shall initial and date the entry to indicate his/her approval. For patients who start their treatment during normal working hours, this shall be done before the initiation of treatment.
3. For patients who start their treatment after normal hours (i.e. on an emergent basis) and the first treatment is prescribed and initiated under the direction of a resident physician, the verbal staff approval for this treatment shall be documented on the prescription sheet by the resident physician. A staff physician shall approve, initial, and date the prescription before the patient receives his/her first treatment during normal working hours.
4. All patient treatment time calculations and other dosimetric calculations or measurements shall be reviewed by a physicist.
5. The treatment charts of all patients under treatment will be reviewed weekly by either a member of the physics staff or a radiation therapy technologist.
6. The above provisions do not apply to total body irradiations done on patients who are about to receive bone marrow transplants. The dose to each anatomical area is checked with entrance and exit dose measurements made with a diode during the course of treatment.
7. All other treatment machine checks and radiation safety practices shall be carried out as specified in the current teletherapy license application, relevant regulations of 10 CFR 35, and specific license conditions.