

NOTICE OF VIOLATION

University of Minnesota
Minneapolis, Minnesota

License No. 22-00187-46
Docket No. 030-00842

During an NRC inspection conducted on June 21-22, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure of NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

1. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

The licensee's quality management program procedure, dated January 22, 1992, Section B(iv) entitled "Verification of Source Preparation," requires the physician/resident whose responsibility it is to load the isotope to verify that the radioisotope, number of sources, source strengths, and loading sequence is in agreement with the written directive and plan of treatment.

Contrary to the above, on June 8, 1993, the licensee's resident physician, an individual under the supervision of an authorized user, did not follow the written quality management procedures established by the licensee. Specifically, the supervised individual failed to verify that the radioisotope, number of sources, source strengths, and loading sequence were in agreement with the written directive prior to administration of a brachytherapy treatment.

This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 35.406(b)(2) requires, in part, that the licensee make a record of brachytherapy source use which must include the number and activity of sources removed from storage and the number and activity of the sources in storage after the removal.

Contrary to the above, on June 8, 1993, the required record was made, however, the activities of the sources removed from storage and the activities of the sources remaining in storage were inaccurate.

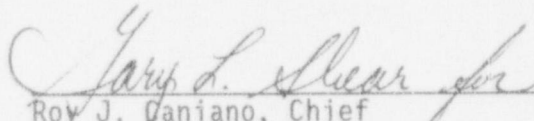
This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, University of Minnesota is hereby required to submit a written statement of explanation to the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or if contested, the basis for disputing the violation,

(2) the corrective steps that have been taken and the results achieved,
(3) the corrective steps that will be taken to avoid further violations, and
(4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

SEP 03 1993

Dated _____


Roy J. Galiano, Chief
Nuclear Materials Safety Branch



THE UNIVERSITY OF CHICAGO
DEPARTMENT OF RADIATION & CELLULAR ONCOLOGY
DIVISION OF THE BIOLOGICAL SCIENCES AND
THE PRITZKER SCHOOL OF MEDICINE

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MELVIN L. GRIEM, M.D.
Professor

University of Chicago Medical Center
5841 South Maryland Avenue, Box 442
Chicago, Illinois 60637

July 19, 1993

Mr. John L. Martin
Regional Administrator
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137-5927

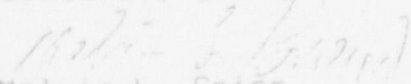
Dear Mr. Martin:

Enclosed is my final report on Preliminary Notification (PN39333) concerning the University of Minnesota medical event. My signed report was sent by FAX several days ago. The enclosed report is the copy I used in that FAX correspondence.

I discussed the report with Mr. Shear today; he was pleased with the report and had no suggestions for further additions to it.

I hope this is helpful in your evaluation.

Sincerely yours,


Melvin L. Griem

Please send US mail to my home address since our hospital mail room causes delays in anything in large envelopes.

That address is:

Melvin L. Griem, M.D.
44 Sunset Trail
Ogden Dunes, IN 46368

~~9308020236~~ 1P.

MEDICAL CONSULTATION REPORT NRC Region III FINAL REPORT 7/14/93
NRC License #22-00187-46 Doc.#PN39333 Rev. M.L.Griem pg1

TO: John B. Martin, Regional Administrator, Reg. III
Gary L. Shear, Chief, Materials Inspection, Section 2
FAX 708-790-5183

FROM: Melvin L. Griem, ACMUI U of Chicago FX312-702-0610
Ph312-702-6883

RE: MEDICAL CONSULTATION REPORT

Signature: *M. L. Griem*

Date: *7/14/93*

Patient identification: C.R.

Individuals contacted: S. Levitt, M.D.; K. E. Dusenbery, M.D.

Records reviewed:

2 documents supplied by Dr. Kathryn E. Dusenbery, M.D.
Initial NRC report 6/18/93
Final Report dated 7/8/93

SUMMARY:

Combined external beam irradiation and two intracavitary cesium brachytherapy courses of treatment were administered to patient C.R. for an advanced cancer of the uterine cervix. Due to a human error the first brachytherapy treatment had a higher dose than planned. This error was discovered and the second brachytherapy course was modified to correct for the problem. Calculations were made and the outcome should be equivalent to the original course planned. No adverse effects should be anticipated. In any case, the prognosis for this patient with a tumor which is FIGO Stage IVA is a very guarded one.

Review of the situation in brief:

The patient has a Squamous Cell Carcinoma of the Cervix stage FIGO IVA. This is a female patient with advanced cancer involving a portion of the uterus at the apex of the vagina with extensive local spread. The treatment as planned was a combination of external beam whole pelvis irradiation of 35 Gy followed by localized external beam irradiation of 10.5 Gy directed to the pelvic wall lymph nodes. This is standard treatment. In addition 2 brachytherapy treatments were planned of equal size using intracavitary sources of radioactive cesium. As a result of the larger size sources the first application of brachytherapy was larger than planned however the second application was reduced to compensate for the larger first application so as to bring the planned dose to be equivalent to that prescribed in the initial treatment plan.

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The questions are the following:

1. Dose to the target area - the same
Dose to the skin, muscle and bone marrow - the same
2. Resultant biological effects expected - no change
Given the data on low dose rate irradiation which was mainly developed by Dr. Eric Hall, of Columbia University and summarized in his book: Radiobiology for the Radiologist, Eric Hall, Harper & Row Pub. Hagerstown, Md. no difference should be expected. Additional data concerning the brachytherapy of this tumor may be found in: Radium Dosage -The Manchester System, W.J. Meredith; Treatment of Malignant Disease by Radiotherapy, Ralston Patterson; as well as the extensive writing of Gilbert Fletcher on the subject. The change in dose rate which occurred with the first brachytherapy application was compensated for with the second procedure. In the low dose rate data the change in dose rate does not have a major change in the outcome considering tumor control or complications.

Follow-up medical care: The standard follow-up procedures should be used. These consist of regularly scheduled office visits with an adequate history, physical examination including a pelvic examination.

3. Opinion on the accuracy of the medical information: The documentation is superb. The final NRC document dated 7/8/93 with the U. Minnesota report and appendices A thru J indicate a very high quality program. The University of Minnesota has been a pioneer in the treatment of tumors of the female pelvis with ionizing radiation. Likewise the medical physics program is recognized as one of the outstanding programs in the United States. Protocols were in place in an attempt to prevent this human error.

Neither the general public or any of the radiation workers were exposed to ionizing radiation differently as a result of the event.

Please contact me if you have any questions. I have more detailed information on the event if you need it.