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PORTER MEMORIAL HOSPITAL

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November 9, 1990

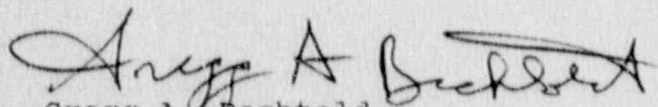
Mr. A. Bert Davis
Regional Administrator
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mr. Davis:

Enclosed is a copy of the proposed audit plan submitted by Drs. Elson and Aron. Please review this plan and provide us with your comments. Once the audit plan has been approved by the NRC, it is our understanding the audit must be completed and a report of the findings submitted to the NRC Regional Administrator within thirty days.

We look forward to your reply.

Sincerely,



Gregg A. Bechtold
Vice President
Professional/Support Services

GAB/ks
Enclosure

cc: Wiley Carr
Bob Welsh
Dr. Boyd
Glen Janssen

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REGION III

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Affiliate of Voluntary Hospitals of America, Inc.

University of Cincinnati
Medical Center



College of Medicine

Department of Radiology
Division of Radiation Oncology

The Barrett Center for Cancer
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November 1, 1990

Mr. Gregg Bechtold
Proter Memorial Hospital
814 LaPorte Avenue
Valparaiso, IN 46383

RE: USNRC License # 13-17073-0
Docket # 030-12150
Letter of 10/25/90 from A.B. Davis to Harris, et al

Dear Mr. Bechtold:

Please find enclosed a proposed audit plan by which we intend to review the brachytherapy program at Proter Memorial Hospital. This plan should fulfill the requirements as stated in the letter of 10/25/90 from A. Bert Davis to Harris, Welsh and Lukman, Attorneys at Law, as well as the previous comments with regard to this issue. As such, please transmit this audit plan to the Regional Administrator, Region II, Glen Ellyn, Illinois.

Upon a satisfactory review of this plan by Region III, USNRC, or the satisfactory resolution of any questions Region III, USNRC might have, the initialization of the brachytherapy review process should begin.

Sincerely yours,

Bernard S. Aron, M.D., FACR
Director, Radiation Oncology

Howard R. Elson, Ph.D.
Associate Professor of Radiology (Physics)
Division of Radiation Oncology

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BRACHYTHERAPY AUDIT PLAN
FOR
PORTER MEMORIAL HOSPITAL
VALPARIASO, IN 46383

- I. PURPOSE: The purpose of this audit is twofold: (1) To review the brachytherapy cases performed under the Porter Memorial Hospital USNRC License (#13-17073-01) to determine if a therapeutic misadministration, as defined by 10 CFR 35.2, has occurred; (2) To review the brachytherapy program and to make recommendations for improvements in the brachytherapy program at Porter Memorial Hospital to prevent the recurrence of any program deficiencies disclosed during the review of the brachytherapy cases.

- II. SCOPE:
 - A. LOCATION: At present, the plan is to conduct the audit remotely from Cincinnati. This, of course, will be totally dependent upon the results of review of documentation, medical records, radiographs and telephone interviews. Upon review of this documentation, it may be deemed necessary to perform an on-site review at Porter Memorial Hospital, Valparaiso, Indiana.

 - B. AUDITORS: The audit will be performed by Bernard S. Aron, M.D. and Howard R. Elson, Ph.D.

 - C. TIME REQUIREMENTS: At present, the auditors understand that a limited number of actual brachytherapy procedures were performed at Porter Memorial Hospital. If this understanding is correct, the review of these procedures should proceed quickly, perhaps less than a week. However, this is totally dependent upon the availability of radiographs, patient records, brachytherapy documentation and dosimetry calculations. Again, with respect to the audit of the brachytherapy program rather than the specific patient treatments, the time required will be dependent upon documentation availability regarding the state of the program. Assuming appropriate documentation is available, the program audit should require less than a week.

 - D. INDIVIDUALS TO BE INTERVIEWED AS PART OF THE AUDIT: The auditors intend to review the brachytherapy procedures performed at Porter Memorial Hospital and determine if any misadministrations have occurred. If it is determined that such events have occurred the audit will proceed to determine the probable cause(s) of the event. This will require information to be obtained from all individuals who can be identified as having participated in the patient treatment. Until the initial stages of the audit have been accomplished, these individuals cannot be identified. With regard to the audit of the brachytherapy program, all individuals involved with the therapeutic administration of brachytherapy sources will be identified and a review of their roles will be reviewed. This will include the medical staff, physics staff, technical staff and the administration staff involved in the program. Again, until the initial stages of the audit have been completed, the specific individuals cannot be identified.

NRC AUDIT (Page Two)

- E. AUDIT OF PATIENT TREATMENTS: It is the intention of the auditors to obtain all documentation of brachytherapy procedures previously accomplished to determine if any misadministration, as defined by 10 CFR 35.2, have occurred. These records should include, but may not be limited to, all radiographs, patient records, dosimetry evaluations, source records, etc., to determine if the treatment dose to the patient was within +/- 10% of the prescribed dose by the use of appropriate sources, geometries, methods and procedures. The auditors intend for these data to be forwarded to the University of Cincinnati Medical Center, Cincinnati, Ohio for evaluation. Again, the identity of the specific information available need be defined in the initial stage of the audit and a method to augment for any unavailable information may need to be devised. It is the intention of the auditors to obtain and/or supplement all information necessary to determine if a misadministration has occurred. Based on this information, it is the auditors' further intention to assess the potential consequences to the patients involved.
- F. AUDIT OF BRACHYTHERAPY PROGRAM TO PREVENT RECURRENCE OF ANY DEFICIENCIES OF THE BRACHYTHERAPY PROGRAM: The extent to which modifications of the brachytherapy program need be accomplished will obviously be dependent upon the present state of the program and the results of the misadministration review. However, the reviewers intend to review the brachytherapy program not only with regard to previous potential misadministrations, but also with regard to an appropriate quality assurance to make every reasonable effort to insure proper patient treatment. This quality assurance program need be performed by adequately trained personnel with appropriate supervision, following written procedures, with an internally administered audit program to insure quality patient care as well as compliance with all regulatory issues. The potential impact of any alterations in the brachytherapy program and the quality assurance program, again, will need to be determined upon review of the present program.
- G. AUDIT REPORT: Within a reasonable time after completion of the brachytherapy audit, a written report will be submitted by the auditors to Porter Memorial Hospital, Valparaiso, Indiana.