

DCD

OCT 25 1990

Harris, Welsh & Lukmann  
Attorneys at Law  
ATTN: Mr. Robert A. Welsh  
107 Broadway  
Chesterton, IN 46304

License No.: 13-17073-01  
Docket No.: 030-12150  
EA 90-072

Gentlemen:

This refers to your letter dated July 30, 1990, requesting NRC review and approval of Dr. Howard R. Elson and Dr. Bernard Aron to conduct the audit of brachytherapy records and files for Porter Memorial Hospital, as required by the NRC's Confirmatory Order dated May 2, 1990 issued to Porter Memorial Hospital. After careful review of the information included with your request and subsequent telephone conversation on September 6, 1990, between Bruce S. Mallett and George M. McCann of my staff and Drs. Elson and Aron, NRC finds both individuals qualified to perform the audit and they are hereby approved to review all appropriate records and patient medical files of Porter's brachytherapy program since program inception.

The next action required by the Order is to submit the audit plan to the Regional Administrator, Region III, for approval. In order to provide you with some guidance on this matter, you should consider the items discussed in the enclosure when proposing your audit plan.

In response to your July 30, 1990, request and in accordance with Section VI.B. of the Order dated May 2, 1990, as last modified on July 25, 1990, the first paragraph of Section VI.B. of the Order is relaxed to read as follows:

"Within 20 days of the NRC approval of the proposed independent auditor, the licensee shall retain said approved auditor and submit the audit plan to the Regional Administrator, Region III, for approval."

All other provisions of the May 2, 1990 Order remain in effect.

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If you have any questions, please contact Mr. John A. Grobe of my staff at (708) 790-5612.

Sincerely,

**Original** signed by  
**A. Bert Davis**

A. Bert Davis  
Regional Administrator

Enclosure: Guidance for  
Proposing the Audit Plans

cc w/enclosure:

W. N. Carr, Porter  
Memorial Hospital  
J. P. Clousson, Esq.

cc w/enclosure, w/ltr  
dtd 07/30/90 w/o enclosure:  
DCD/DCB (RIDS)

bcc w/enclosure, w/ltr  
dtd 07/30/90 w/o enclosure:  
J. Lieberman, OE  
J. Goldberg, OGC  
G. Holler, OGC  
R. Bernero, NMSS  
J. Glenn, NMSS  
J. Mullauer, NMSS

*yes*  
 RIII  
 MW/ayer/01  
 10/18/90  
 RIII  
 Davis  
 10/20/90

*yes*  
 RIII  
 WWS  
 Schultz  
 10-18-90  
 NMSS  
 Glenn  
 10/17

*yes*  
 RIII  
 Grobe  
 10/16  
 OGC  
 Goldberg  
 10/15

RIII  
 Berson  
 10/16  
 OE  
 Lieberman  
 10/17

RIII  
 Pederson  
 10/16  
 NMSS  
 Paperiello  
 10/24/90

RIII  
 Paperiello  
 10/24/90

Guidance for Proposing the Audit Plans

One purpose of the audit is to review brachytherapy cases performed under the Porter Memorial Hospital license to determine whether or not misadministrations as defined by 10 CFR 35.2 occurred. In order to provide you with guidance concerning the audit plan, the following items need, as a minimum, to be addressed:

1. Time needed to complete the audit.
2. Where the audit will take place.
3. Who will be present during the audit and what persons will be interviewed during the audit.
4. What brachytherapy records and radiographs, etc., will be reviewed. This review needs to include all records and radiographs that were used by the physicist and physician during treatment planning, implant, duration of treatment, and explant.
5. Whether each radiation dose was prescribed and recorded prior to treatment.
6. Whether there were any changes to the prescribed dose or treatment plan during treatment. If so, were these changes a result of medical decisions made at the time of the change and were the reasons for the changes, including the date of the changes, documented.
7. Whether each radiation dose was administered to the area of interest as prescribed. For example:
  - a. Were the correct sealed sources used?
  - b. Was the treatment plan performed prior to implant and was the treatment plan adequate to implement the physician prescribed dose?
  - c. Was the administration to the correct patient?
  - d. Was the route of administration as prescribed?
  - e. Were the sealed sources calibrated properly?
  - f. Was the treatment geometry correct to deliver the dose to the prescribed location?
8. Was the final dose within  $\pm 10\%$  of the prescribed dose?

The second purpose of the audit is to make recommendations for improvements in the brachytherapy program at Porter Memorial Hospital to prevent recurrence of any deficiencies disclosed during the review of brachytherapy cases. In evaluating the program to identify improvements, your auditors should examine, as a minimum:

1. The adequacy of staffing levels, qualifications, and training.
2. The effectiveness of communication between the involved personnel.
3. The adequacy and implementation of written guidance and procedures for conducting brachytherapy activities.
4. The sufficiency of documentation and records of brachytherapy procedures.
5. The adequacy and effectiveness of the licensee's staff and administration's oversight and supervision of brachytherapy activities conducted under its license including internal audits for self-identification of problems.
6. The adequacy of the independent verifications to ensure brachytherapy activities are conducted in accordance with license requirements.