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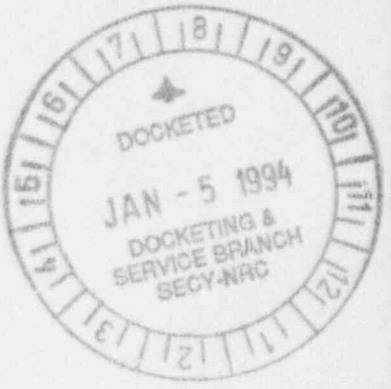

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

IN THE MATTER OF	)	Docket No. 030-30485-EA
	)	License No. 37-28179-01
INDIANA REGIONAL CANCER CENTER	)	EA No. 93-284

RESPONSE OF INDIANA REGIONAL CANCER CENTER
TO DEMAND FOR INFORMATION

Indiana Regional Cancer Center files this Response To The NRC's Demand For Information and in support thereof states as follows:

1. The Answer Of James E. Bauer, M.D., M. Div. And Indiana Regional Cancer Center To November 16th Order Suspending License No. 37-28179-01 Of Indiana Regional Cancer Center is incorporated herein by reference and made a part hereof.

2. A copy of the November 11, 1993 inspection report is incorporated herein by reference, relied upon and attached hereto as exhibit 1.

3. The RSO and authorized user under license 37-28179-01, Dr. Bauer, is a highly competent board certified radiation oncologist and radiologist with in excess of thirty years experience in the safe use of radioactive materials.

4. The November 11, 1993 inspection revealed:

   (A) No radiation safety violations;

   (B) Full training in the Quality Management Program had been provided;

   (C) The strontium-90 source was secured and the storage area was posted as required;

   (D) The licensee had available two Victoreen 410 meters. Both meters were calibrated and the

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inspectors verified that the staff had been trained on how to perform check source readings to ensure operability of the meters;

(E) The inspector noted that the licensee performed ambient dose rate surveys around the source storage location approximately quarterly;

(F) The inspector noted that all sealed source leak tests and inventories of the strontium-90 sealed source were conducted by the licensee as required;

(G) The inspector noted that personnel had available the required personnel dosimetry;

(H) The inspector determined that the licensee followed the Quality Management Program when performing the strontium-90 treatments;

(I) No individuals were harmed in any manner;

(J) There was absolutely no risk to public health and safety;

(K) Dr. Bauer believed he was permitted to use the strontium-90 source for superficial skin lesion treatment;

(L) Dr. Bauer fully and truthfully responded to all questions; and

(M) Dr. Bauer provided all requested information to the inspectors on November 11, 1993.

5. Based on the extensive experience of Dr. Bauer the use of strontium-90 for the treatment of superficial skin lesions is medically appropriate.

6. The NRC has not even attempted to levy any civil fine for the alleged "failure to do an adequate survey in November 1992" by Dr. Bauer. To now assert that said contested and undetermined "issue" is a "fact" is unconstitutional, improper, a denial of due process, unethical and in violation of all applicable regulations. Further, the NRC has admitted that Dr. Bauer did not violate any license condition in November 1992 by allegedly failing to do an adequate survey. The only basis on which the NRC relies is the general language of 10 CFR 20.201(b). See exhibit 2 hereto. Moreover, the

alleged violation in November 1992 had absolutely nothing to do with the license at issue herein.

7. The licensee's past performance has been exemplary, as the 1989 inspection clearly indicated.

8. The NRC has stated, without any adequate basis, that the public safety was threatened by the conduct of the licensee and Dr. Bauer. Such is not the case and strict proof thereof will be demanded at the hearing.

9. There exists no basis for the NRC to believe that the Licensee will not comply with all Commission requirements. To the contrary, the Licensee has in the past and will at all times in the future continue to use its best efforts to fully comply with all Commission requirements.

10. To revoke the subject license would constitute a travesty of injustice to the licensee, cancer patients and society in general. Dr. Bauer is a highly competent and ethical practitioner, radiation safety officer and authorized user. Moreover, other proposed licensed activities of the Licensee indicate that Dr. Roger Tokars will be the RSO and authorized user.

11. There has never been any finding that the licensee or Dr. Bauer willfully or negligently violated any federal regulations or that either improperly uses or have improperly used radioactive materials.

12. The licensee and Dr. Bauer are both willing and able to assure the Commission that all NRC regulations have been, are being and will continue to be followed.

WHEREFORE, there exists no basis, at law or in fact, to (1) bar, revoke or modify the Indiana Regional Cancer Center's license; (2) to bar the Indiana Regional Cancer Center from the use of any radioactive material; or (3) to continue the suspension. The suspension should be immediately lifted. Indiana Regional Cancer Center reserves the right to supplement this response as necessary and appropriate at a later date.

Respectfully submitted,

Iles Cooper

Iles Cooper
Williamson, Friedberg & Jones
P.O. Box E
One Norwegian Plaza
Indiana, PA 15701-0607
(717) 622-5933

Counsel for Indiana Regional Cancer Center

Dated: January 5, 1994

DETAILS

1. Persons Contacted

*James E. Bauer, M.D., Medical Director and Radiation Safety Officer
*Marcy Colkitt, Counsel
Pat Korywchak, Nurse
Charlene Santes, Secretary
Mitch Jarosz, Consultant

*Present at Exit Conference on November 11, 1993

2. Scope

The licensee currently has an NRC license that authorizes treatment of superficial eye conditions with a strontium-90 medical eye applicator. The licensee stated that 6 to 7 patients are treated per year with the strontium-90 source.

The Radiation Safety Officer (RSO) and only authorized user was asked by the inspectors about the treatment modalities for which the source was used. The RSO stated that he used the source for treatment of pterygium, an eye condition. The inspectors asked the RSO if he used the source for any other treatment modality. The RSO stated again that the source had been used for treatment of pterygium. When asked to provide the last six patients' files for review, the RSO provided a patient file that showed treatment for pterygium in June and July of 1993.

The inspectors then asked the secretary for and received a patient scheduling log for the year. Upon review of the log, the inspectors determined that two patients had been treated recently (September, October, and up to November 11, 1993). Upon review of the files, the patients were found to have been treated with the strontium-90 source for skin lesions, a treatment modality not authorized by the license. The first patient was treated from September 20, 1993 to October 25, 1993, for a skin lesion on the tip of the nose with a total dose of 4500 centigray delivered over 6 fractions of 750 centigray each. The second patient was treated from October 21, 1993 to November 11, 1993 (immediately prior to the inspection) for a skin lesion on the nose and a skin lesion on the face with four fractions delivered of 750 centigray each. The second patient was prescribed to have two additional treatments of 750 centigray each to complete the treatment.

10 CFR 30.3 requires, in part, that except for persons exempted, no person shall use byproduct material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Areas Inspected: Scope of licensee program; organization; training; facilities and equipment; use of material; personnel radiation protection; waste disposal; misadministrations; and quality management program.

Results: Two apparent violations were identified: 1) use of byproduct material not authorized by a specific license issued pursuant to 10 CFR Parts 30 and 35 (Section 2); and 2) failure to provide complete and accurate information pursuant to 10 CFR 30.9 (Section 2).

bcc:
Region I Docket Room (w/concurrences)
T.T. Martin, RI
W.F. Kane, RI
C.J. Paperiello, NMSS
C.W. Hehl, RI
S.F. Shankman, RI
S.H. Lewis, OGC
J. Lieberman, OE
J.E. Glenn, NMSS
R.R. Bellamy, RI
J.R. DelMedico, OE
K.D. Smith, RI
D.J. Holody, RI
M. Banerjee, RI
J.M. Johansen, RI
P.A. Nessen, RI
S.W. Shaffer, RI

Condition 9 of License No. 37-28179-01 issued pursuant to Parts 30 and 35 limits the authorized use of the strontium 90 medical eye applicator to the treatment of superficial eye conditions.

Use of byproduct material, except as authorized by License Condition 9, is an apparent violation of 10 CFR 30.3 and Condition 9 of License No. 37-28179-01.

10 CFR 30.9 requires, in part that information provided to the Commission by a licensee be complete and accurate in all material respects.

Failure of the RSO to provide complete and accurate information to the inspectors when questioned about the use of the strontium-90 source is an apparent violation of 10 CFR 30.9.

3. Organization

Dr James E. Bauer is the Medical Director, the RSO, and the sole authorized user for this license. Dr. Bauer uses the services of a consultant to perform sealed source leak tests, sealed source inventories, sealed source storage surveys, and radiation safety training. Dr. Bauer also uses the services of Ms. Marcy Colkitt for legal counsel related to this license.

4. Training

The consultant provided training in November of 1993 on the Quality Management Program as it relates to any therapy treatment, including strontium-90. The RSO stated that he provided the nurse additional training on radiation safety as it applied to the use of the strontium-90 source.

5. Facilities and Equipment

a. Facilities

The licensee is licensed for use in a specific room located at 877 Hospital Road. The strontium-90 source was locked in a cabinet within this room. The storage area containing the strontium-90 source was posted as required.

b. Equipment

The licensee had available two Victoreen 410 meters with a range of 0.1 milli-Roentgen per hour to 1 Roentgen per hour. Both meters were calibrated as required. The inspectors also verified that licensee staff had been trained on how to perform check source readings to ensure operability of the meters.

6. Use of Materials

The inspectors reviewed the quarterly ambient surveys performed around the source storage area and the leak tests and inventories performed of the source.

a. Area Ambient Surveys

The inspector noted that the licensee performs ambient dose rate surveys around the source storage location approximately quarterly. When a transition was made by the licensee in 1993 to a new consultant the surveys were performed late, however the licensee identified the oversight and performed subsequent surveys as required. Records are maintained of the surveys as required. Because the surveys were peformed within 30 days after the calendar quarter ended and the licensee identified and corrected this oversight, this violation is not being cited.

b. Sealed Source Leak Test and Inventory

The inspector noted that all sealed source leak tests and inventories of the strontium-90 sealed source were conducted as required. As discussed above, during the transition to a new consultant the leak test and inventory were performed late, however subsequent leak tests and inventories have been performed on schedule. Records are maintained of the leak tests and inventories as required. Because the leak tests and inventories were peformed within 30 days after the required frequency ended and the licensee identified and corrected this oversight, this violation is not being cited.

7. Personnel Radiation Protection

The inspector noted, on the day of the inspection, that personnel had available the required personnel dosimetry. Records of personnel exposure were reviewed from January 5, 1993 to September 4, 1993. Records were not reviewed for the period from the last inspection, January 1989, to December 1992 since these records were reviewed previously during the investigation in December 1992 of an event at the Center. The licensee uses vendor dosimeters which are exchanged monthly. The

licensee's RSO reviewed and investigated one exposure that occurred in June of 1993 where the nurse received 100 millirem whole body dose from a beta source. The nurse was retrained on radiation hazards associated with the strontium-90 source and instructed that when assisting the RSO during treatments, maximum distance should be observed as far away from the source as possible.

8. Waste Disposal

The licensee has not disposed of any strontium-90 sources since the previous inspection conducted in 1989.

9. Misadministrations

The licensee's RSO stated that no misadministrations had occurred with the strontium-90 source.

10. Quality Management Program

The inspector determined that the licensee had implemented the quality management program that was submitted to the NRC for Oncology Services Corporation's license. The inspector also determined that the licensee had followed the quality management program when performing the strontium-90 treatments.

11. Exit Interview

The inspector met with the licensee's representatives designated in Section 1 of this report at the conclusion of the inspection. The inspector summarized the scope and findings of the inspection.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DEC 3 0 1993

Marcy L. Colkitt, Esq.
Post Office Box 607
Indiana, Pennsylvania 15701-0607

Dear Ms. Colkitt:

This responds to your letter of December 23, 1993 requesting further specificity as to the legal basis regarding the failure to conduct a survey cited in our Order Modifying and Suspending License of November 16, 1993. That Order refers to the November 1992 incident at Indiana Regional Cancer Center which was addressed in our Order Suspending License of January 20, 1993 issued to Oncology Services Corporation. The January 20, 1993 Order states on page 3:

> In addition, 10 CFR 20.201(b) requires that the Licensee make such surveys as (1) may be necessary to comply with the regulations in 10 CFR Part 20 and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

This statement provides the basis for the reference in the November Order to failure to cause an adequate survey to be made.

I trust this answers your question.

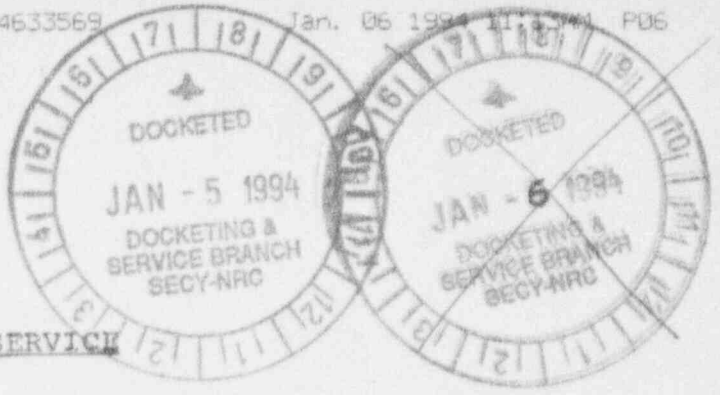
Sincerely,

James Lieberman, Director
Office of Enforcement

CC:
G. Paul Bollwerk, III Administrative Judge
Dr. Peter S. Lam, Administrative Judge
Dr. Charles N. Kelber, Administrative Judge

VERIFICATION

Based upon the representations of James E. Bauer the foregoing is true and accurate to the best of my knowledge, information or belief.



CERTIFICATE OF SERVICE

This 5th day of January, 1994, the foregoing Response Of Indiana Regional Cancer Center To Demand For Information was served on the following as indicated:

James Lieberman, Esquire
Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
(via telecopy: 301-504-2260 and U.S. Mail)

Mr. Lawrence J. Chandler
Assistant General Counsel for Hearings
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
(via U.S. Mail)

Thomas J. Martin, Regional Administrator
Nuclear Regulatory Commission
Region I
475 Allendale Road
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Secretary
U.S. Nuclear Regulatory Commission
Attn: Chief, Docketing and Service Section
Washington, D.C. 20555
(via telecopy: 202-504-1672)

Marian L. Zobler, Esq.
Office of General Counsel
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
(via U.S. Mail)

Iles Cooper