UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

IN THE MATTER OF) Docket No. 030-30485 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.
- 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

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.
- 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,

Ten Coppel

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Dated: January 5, 1994