

*Richhold*

NUCLEAR MEDICINE CENTER  
R. S. MANOLI, M.D.  
(IN VIVO, IN VITRO AND NUCLEAR CARDIOLOGY)

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EPHONE  
453-6565  
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October 18, 1993

Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137-5927

Dear Mr. B.J. Holt:

This is in response to your letter dated October 5, 1993 regarding our violations of NRC requirements. The specified requirements have been rectified with the enclosed form, this should include procedures 1-4 on your enclosed list of procedures. We have already started the fifth procedure listed per your request.

I hope this is sufficient response for the violations and the enclosed form is supplying the necessary requirements. We will certainly be more conscientious of this very important matter in the future and hope it will not happen again. If there are any other questions please contact my office at 453-6565.

Thank you,

*R.S. Manoli*  
R.S. Manoli, M.D.

9402160048 931230  
PDR ADOCK 03018480  
C PDR

OCT 21 1993

NUCLEAR MEDICINE CENTER  
10425 W. NORTH AVE.  
MILWAUKEE, WI 53226

CONSENT TO RADIONUCLIDE THYROID THERAPY

PATIENT \_\_\_\_\_ DATE \_\_\_\_\_

TIME \_\_\_\_\_

1. I hereby authorize Dr. \_\_\_\_\_ and/or such assistants as may be selected by him, to perform radionuclide thyroid ablation therapy to treat the condition of hyperthyroidism which appears indicated by the diagnostic studies already performed.

\_\_\_\_\_  
(Explain the nature of the condition and the need to treat such condition)

2. The therapy necessary to treat my condition of hyperthyroidism and the alternative methods of treatment have been explained to me in laymen's language by Dr. \_\_\_\_\_ and I understand the nature of the therapy to be:

\_\_\_\_\_  
(A description of the procedure(s) in the language of laymen)

3. I have been made aware of certain risks and consequences that are associated with the therapy described in paragraph 2, such as developing a hypothyroid condition.

4. I am aware that the practice of medicine is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of the radionuclide thyroid ablation therapy for the treatment of hyperthyroidism.

5. I hereby authorize Dr. \_\_\_\_\_ and/or such assistants as may be selected by him, to administer to the above-named patient  $\text{Na}^{131}\text{I}$  for the treatment of hyperthyroidism.

I acknowledge that I have read the above and foregoing and fully understand it.

\_\_\_\_\_  
(Witness)

\_\_\_\_\_  
Signature of Patient

Patient is unable to sign because of \_\_\_\_\_

\_\_\_\_\_  
(Witness)

\_\_\_\_\_  
(Closest Relative or Legal Guardian)

I have explained the matters indicated above relating to the  $\text{Na}^{131}\text{I}$  thyroid ablation therapy for the treatment of hyperthyroidism and the risks, consequences and alternatives. The patient and/or the relative indicated appeared to understand and consented to the radionuclide thyroid ablation therapy.

Physician \_\_\_\_\_

AUTHORIZATION FORM TO ORDER

Na<sup>131</sup>I FOR THE TREATMENT OF HYPERTHYROIDISM

I authorize the ordering of \_\_\_\_\_ millicuries of Na<sup>131</sup>I to be utilized in the treatment of the hyperthyroid condition of \_\_\_\_\_.

Dr. \_\_\_\_\_

Dose Calibrator Reading \_\_\_\_\_ x  $\frac{\text{correction}}{\text{factor}}$  = \_\_\_\_\_ tech. initials

Activity Authorized \_\_\_\_\_ +10% ' -10%

Is the corrected dose calibrator reading within  $\pm 10\%$  of the authorized activity level (yes/no).

IF NO, CONTACT THE AUTHORIZING PHYSICIAN. An administration not within  $\pm 10\%$  of the authorized activity will result in a misadministration.

Patient's Name \_\_\_\_\_

Amount administered \_\_\_\_\_ millicuries.

Date Administered \_\_\_\_\_ Time \_\_\_\_\_

Administered by Dr. \_\_\_\_\_

Supervised by Dr. \_\_\_\_\_