



May 17, 2005

US Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, Texas 76011-4005

Dr. Alan L. Mitchell, RSO
Campbell County Memorial Hospital
501 S. Burma Ave., P.O. Box 3011
Gillette, WY 82717

SUBJECT: REPLY to a NOTICE of VIOLATION, REPORT 030-14365/05-001

Dear Sir or Madam:

This letter is in response to the notice of violation dated April 26, 2005, received by Campbell County Memorial Hospital in Gillette, Wyoming. As you are aware there was recently a violation where the licensee failed to provide instruction to two nuclear medicine technologists on the written directive procedure. As to the reason for this violation it appears to have simply been an oversight although I seem to recall that in discussion with the inspector on the day of our review, this policy may have been new and not realized. In either case, the violation did occur and we have taken the following corrective steps to be in compliance. Attached, you will find a form which is now part of our procedure labeled I-131 Written Directive. Although I do not recall the exact date that this went in to affect, it had already been accepted and put in place in the protocol prior to receiving your notice of violation. Also attached is a copy of the form titled Disclosure for Treatment and Therapy for Hyperthyroidism. This form contains much of the same information required in the written directive and was already in place prior to your inspection. We hope that this is more than adequate. In either case, if you could be so kind as to send a reply so that we can be certain that we are indeed in compliance or if there are additional changes or requirements that need to be met.

Your understanding and consideration of this matter is greatly appreciated.

Sincerely,

Alan L. Mitchell, M.D.
Radiation Safety Officer

CAMPBELL COUNTY MEMORIAL HOSPITAL
501 SOUTH BURMA AVENUE
GILLETTE, WYOMING 82716

I131 WRITTEN DIRECTIVE

1. Order received from Doctor Yes No NA
2. Patient scheduled for I131 dose Yes No NA
3. Pregnancy test performed Yes No NA
4. I131 Dose ordered Yes No NA
5. I131 received and recorded in log book Yes No NA
6. Patient verification name, DOB Yes No NA
7. Patient given consent and pamphlet Yes No NA
8. Radiologist answer questions and gives dose
 Dr. Mitchell
 Dr. Lawrence
 Ordered Dose
 Dose received

Date: _____

Time: _____

Technologist: _____

Prescription:

CAMPBELL COUNTY MEMORIAL HOSPITAL
 RADIOLOGY
 DISCLOSURE FOR TREATMENT OF HYPERTHYROIDISM I-131
 THERAPY FOR DIFFUSE HYPERTHYROIDISM
 NUCLEAR MEDICINE SERVICE

YOUR PHYSICIAN HAS REFERRED YOU FOR A TREATMENT DOSE OF RADIOACTIVE IODINE FOR HYPERTHYROIDISM (OVERACTIVE THYROID GLAND). OTHER METHODS OF THERAPY MAY BE AVAILABLE, BUT THIS PARTICULAR TREATMENT IS FELT TO BE BEST IN YOUR SITUATION AT THIS TIME.

WE ARE ATTEMPTING TO RETURN YOU TO A NORMAL THYROID STATE BY DESTROYING PART OF YOUR THYROID GLAND CELLS. RESULTS ARE NOT ALWAYS SUCCESSFUL. THERE IS AN APPROXIMATELY 10% CHANCE THAT THE TREATMENT WILL NOT DECREASE YOUR THYROID GLAND FUNCTION TO NORMAL. IN THIS CASE AN ADDITIONAL TREATMENT WILL BE NECESSARY.

ON THE OTHER HAND, THERE IS AN APPROXIMATELY 20% CHANCE THAT THE TREATMENT WILL DECREASE YOUR THYROID GLAND FUNCTION BELOW NORMAL IN THE FIRST YEAR FOLLOWING TREATMENT, AND THIS PERCENTAGE INCREASES THEREAFTER AT ABOUT 5% PER YEAR. IN ADDITION, IT SHOULD BE NOTED THAT OVER TIME THE NATURAL COURSE OF HYPERTHYROIDISM MAY LEAD TO HYPOTHYROIDISM (TOO LITTLE THYROID FUNCTION).

IF YOUR THYROID FUNCTION BECOMES LESS THAN NORMAL, YOU WILL NEED TO TAKE REPLACEMENT THYROID HORMONE. BECAUSE THIS MAY HAPPEN IN THE FUTURE, YOU SHOULD SEE A PHYSICIAN PERIODICALLY, e.g. ONCE A YEAR, FOR THE REST OF YOUR LIFE TO BE SURE THAT THE AMOUNT OF THYROID HORMONE IN YOUR BLOOD IS NORMAL.

THERE ARE TWO MINOR, SELF-LIMITED, SIDE EFFECTS WHICH MAY OCCUR. FIRST, THERE IS A 1% OR LESS CHANCE THAT THE TREATMENT MAY MAKE YOUR THYROID CONDITION WORSE FOR 1 TO 3 DAYS. SECOND, THERE IS A 1% OR LESS CHANCE THAT THE TREATMENT WILL MAKE YOUR SALIVARY GLANDS SORE FOR 1 OR 3 DAYS. IF EITHER OF THESE COMPLICATIONS OCCUR, YOU MAY CONTACT YOUR PHYSICIAN FOR SYMPTOMATIC TREATMENT.

IF YOU HAVE GRAVES OPHTHALMOPATHY (POTRUSION OF THE EYES), THIS CONDITION MAY WORSEN FOLLOWING TREATMENT WITH RADIOACTIVE IODINE.

FEMALE PATIENTS WHO MAY BE PREGNANT OR NURSING SHOULD NOT UNDERGO THE TREATMENT.

 PATIENT OF LEGAL GUARDIAN

 PHYSICIAN

 WITNESS

 DATE

REFERRAL INFORMATION

REFERRING PHYSICIAN _____

PATIENT NAME _____

IMAGING FINDINGS _____

UPTAKE VALUES: 4 HR _____% 24 HR _____%

HORMONE LEVELS _____

DIAGNOSIS _____

OFF PTU ≥ 7 DAYS _____ YES _____ NO

NO IV CONTRAST ≥ 6 WEEKS _____ YES _____ NO

OPHTHALMOPATHY _____

ON CORTICOSTEROIDS _____

DOSE OF I-131 TO BE ORDERED _____

TREATMENT DATE _____

NUCLEAR MEDICINE PHYSICIAN _____

TODAY'S DATE _____