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MEDICAL PHYSICS CONSULTANTS, INC.

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800-321-2207

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ANN ARBOR, MI 48103
313-662-3197

B. J. Holt
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532

May 25, 1994

DOCKET # 030-01586

Dear Ms. Holt:

As required in the CONFIRMATORY ORDER MODIFYING LICENSE to Ball Memorial Hospital, NRC License 13-00951-03, dated October 20, 1993, I am forwarding to you the report of my monthly audit of the ıll Memorial Hospital radiation safety program on May 20, 1994.

If you have any questions regarding this information, please call the 800 number on the letterhead and leave a message and I will get back to you as soon as possible.

Sincerely,

Robert T. Anger, Jr.

Robert T. Anger, Jr., M.S.
ABR Certified Medical Nuclear Physicist

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May 24, 1994

Mitchell Carson
Vice President, Operations
Ball Memorial Hospital
2401 West University Avenue
Muncie, IN 47303

Dear Mitch:

In accordance with the NRC's CONFIRMATORY ORDER MODIFYING LICENSE dated October 20, 1993, I am providing a report of my monthly audit conducted May 20, 1994. A copy will also be forwarded to B. J. Holt at the NRC Region III office.

The visit began with the scheduled 7:00 am meeting with administration and authorized users:

Discussion

1. The NRC visit on Wednesday, May 18, turned out to be an audit of the bone scan incident, the hospital's response to each of the items identified in the CONFIRMATORY ORDER MODIFYING LICENSE, and the monthly/quarterly MPC audits. I'm not sure why the NRC chose not to inform the hospital that the visit would cover more than the bone scan incident. I would have found it helpful to have participated in the discussion regarding the confirmatory order items and the MPC audits (particularly the monthly audits that I have been performing).

2. I mentioned the recent incident involving a 5 mCi hyperthyroid treatment dose administered to a patient who subsequently turned out to be in the 5th month of pregnancy, even though she denied any possibility of pregnancy at the time of treatment. Even though the NRC has not required or suggested it (yet), the Quality Management Plan should probably address this issue for treatment of females of childbearing age. As a followup note to this discussion, it is my understanding that the NRC does not consider this incident to be a therapeutic misadministration.

3. There was continued discussion of staffing in Nuclear Medicine. A fourth full-time technologist will be starting in July and another of the Ball State NMT program graduates will be available for part-time coverage at that same time. It was noted that it is difficult to fully resolve the staffing issue until the NRC has completed its investigation.

4. I am still working on specific procedures to provide assurance that authorized users are meeting their responsibilities.

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I reviewed three I-131 hyperthyroid therapy procedures done since my last visit. All was in order except that the technologist handling a therapy dose administered on 5/16/94 had not yet had his thyroid counted. I brought this to his attention and the bioassay was done on 5/20/94 and there was no measurable thyroid burden. I reminded the technologist that the bioassay should be performed between 24 and 72 hours after handling the therapy dose.

Although not mentioned in the report of my last visit, the written directive problems identified that day were shown to both Dr. Ericson and Dr. Leiphart (because they were readily available) with the assumption that this information would be passed on to the other authorized users. Dr. Ericson was the only authorized user who attended the QM Plan inservice on October 29, 1994. It is essential that all of the physicians authorized for radionuclide therapy procedures be familiar with the QM Plan. At the very least, each appropriate authorized user should document that he has read and understands the QM Plan. Preferably, there should be an "inservice" for the appropriate physicians with mandated attendance. Either Ed or I could do it, but scheduling may be a problem. Perhaps it could be done by the RSO (or possibly Dr. Ericson since he attended my inservice) using the materials from my Oct. 29 inservice.

The minimum detectable activity (MDA) for I-131 thyroid bioassays is 22 cpm (0.0066 uCi) as last determined on 9/24/93. The significance of the MDA in cpm is that it represents the minimum net cpm that is distinguishable from background. Thus, when a thyroid bioassay results in a net cpm that is ≤ 22 cpm, the associated thyroid burden should be recorded as "≤ 0.0066 uCi". There is no statistical justification for converting net cpm values ≤ 22 cpm into uCi.

Since the thyroid bioassay results are actually part of each individual's personnel monitoring record, it would probably make more sense to have a separate results sheet for each individual monitored. A copy could then easily be provided to an individual upon request.

I have asked Ed to formally review the bioassay procedure with the technologists. Also, I have provided another original of the revised written directive form that contains a place for the technologists to document the bioassay result.

I observed Ed Wroblewski reviewing the patient dosage records for the past week in both the main department and in Nuclear Cardiology. I reviewed the patient dosage records since my last visit and found them to be in compliance with the verification system described in BMH's letter and enclosures to the NRC dated Aug. 5, 1993.

If you have any questions regarding this information, please let me know. As decided at our morning meeting, my next visit will be June 17, 1994.

Sincerely,

Original signed by

Robert T. Anger, Jr., M.S., M.P.H.
ABR Certified Medical Nuclear Physicist

BALL MEMORIAL HOSPITAL
DEPARTMENT OF NUCLEAR MEDICINE
QUALITY MANAGEMENT PLAN WORKSHEET

RADIOPHARMACEUTICAL THERAPY OR NAI I-125 OR I-131 > 30 UCI

WRITTEN DIRECTIVE:

PATIENT NAME:_____ BIRTH DATE:_____

RADIOLOGY NUMBER: _____

PROCEDURE:_____

DOSAGE	RADIOPHARMACEUTICAL	ROUTE OF ADMINISTRATION
_____	I-131 Sodium Iodide	Oral
_____	_____	_____

_____ M.D. DATE: _____

Signature of Authorized User

INTENT OF WRITTEN DIRECTIVE UNDERSTOOD:

Person preparing radiopharmaceutical: _____

Person administering radiopharmaceutical: _____ .

BIOASSAY RESULTS

Name:_____ Date:_____ _____uCi

Name:_____ Date:_____ _____uCi

RADIOPHARMACEUTICAL LABEL

DOSE ASSAY VERIFICATION

Dose Calibrator Sticker

Technologist: _____

Auth. User: _____ M.D.

PATIENT VERIFICATION (AT LEAST 2)

- patient asked name ☐
- wrist band checked ☐
- patient asked to spell name ☐
- patient asked to state birth date ☐
- patient asked to state address ☐
- patient asked for drivers license ☐
- other _____ ☐

ROBERT T. ANGER, JR.
MEDICAL PHYSICS CONSULTANTS, INC.

9100 Meridian Square
70 E. 91st Street, Suite 106
Indianapolis, Indiana 46240

USA 29

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