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BALL MEMORIAL HOSPITAL

May 26, 1994

Ms. B. J. Holt, Chief
U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Inspection - Section I
801 Warrenville Road
Lisle, IL 60532-4351

Dear Ms. Holt:

Subject: USNRC License #13-00951-03 Docket # 030-01586

Ms. Toye Simmons and Ms. Michelle Barry, Radiation Specialists from the U.S.N.R.C. Region III, completed a review on May 18, 1994, of the recent incident involving a bone scan performed by our nuclear cardiology department, our monthly and quarterly audits performed by Medical Physics Consultants, and our Confirmatory Order Modifying License. One of the inspectors noted there was no written Policy or Procedure for the compliance of Item IV-A of the Order. The inspector felt although a system had been developed and implemented at the time of the receipt of the Order, a more formal written document was necessary. Attached for your records, is a copy of our written policy and procedure which outlines the system we developed. We have also enclosed the following documents:

1. Policy and Procedure for Confirmatory Order Modifying License Item IV-A;
2. Radiopharmacy order sheet;
3. Consultation worksheet; and
4. Package order and receipt procedures approved by the U.S.N.R.C. with the issuance of amendment #41 on March 25, 1994.

Our Radiation Safety Committee will convene on June 15, 1994, to discuss this policy and procedure to assure continued compliance with NRC regulations.

Please let me know if you have any questions or need additional information.

Cordially,

Mitchell C. Carson
Vice President, Operations

/mcm

Attachments

cc: Toye Simmons, Radiation Specialist
Charles Leibhart, M.D.
Jay Veenendaal, M.D., Interim Radiation Safety Officer
Ed Wroblewski, ARSO

MAY 31 1994

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Ball Memorial Hospital, Inc.
Radiology Services
Nuclear Medicine Section

Confirmaty Order Modifying License, Item IV-A, Policy and Procedure:

Policy: A unit dose system has been established for the Nuclear Medicine Section at Ball Memorial Hospital. The unit doses originate from a radiopharmacy vendor outside this facility. All unit doses and generator orders for radiopharmaceuticals are made by an authorized user named on license #13-00951-03 or the Assistant Director of Radiology or his designee. The designee is not a nuclear medicine technologist or an employee of the nuclear medicine section.

Procedure for radiopharmaceutical requests: Inpatient requests for patient studies are received in radiology from any given nursing unit at any time. Outpatient requests are scheduled directly in nuclear medicine. The day preceding patient studies, the nuclear medicine technologist on the radiopharmacy rotation will generate the *Radiopharmacy Order Sheet* (Attachment I). The *Radiopharmacy Order Sheet* indicates the following information:

1. Desired activity;
2. Radiopharmaceutical chemical name;
3. Requested calibration time;
4. Type of exam;
5. Patient name;
6. Date for order request;
7. Technologist initiating the *Radiopharmacy Order Sheet*;
8. Date of call to radiopharmacy vendor; and
9. Signature or initials of person initiating call to radiopharmacy vendor.

Upon completion of the *Radiopharmacy Order Sheet* by the nuclear medicine technologist, an authorized user either signs or initials and dates this document. A copy is made for the nuclear medicine technologist on the radiopharmacy rotation. In addition to the *Radiopharmacy Order Sheet*, an individual patient *Consultation Worksheet* (Attachment II) is generated. The individual *Consultation Worksheet* contains similar information as documented on the *Radiopharmacy Order Sheet* with the exception of items 3, 8 and 9. The *Consultation Worksheet* requires the authorized user(s) to verify the appropriateness of the exam ordered. The *Consultation Worksheet* is returned to the nuclear medicine hot lab for assay preparation. The *Consultation Worksheet* contains the signature and date of the authorized user who reviews the case. Any deviations from the prescribed dose range are approved and initialed by the authorized user. Any nonroutine doses are discussed with the authorized user and the nuclear medicine technologist involved in the study prior to radiopharmaceutical administration.

Next day deliveries are verified against the *Radiopharmacy Order Sheet* by the nuclear medicine technologist on the radiopharmacy rotation. Nuclear Medicine technologists may notify the radiopharmacy vendor of any cancellations.

This policy and procedure will be reviewed and approved by the Radiation Safety Committee on June 15, 1994.

SYNCOR TOLL FREE 1-800-183-0277

ATTACHMENT I.

SYNCOR ORDER SHEET

Date _____
Tech _____

Dr. _____

DOSE AMT	RRX	TIME CALIBRATED	EXAM	PATIENT NAME

Date called _____
Called by _____

ATTACHMENT II.

BALL MEMORIAL HOSPITAL
NUCLEAR MEDICINE SECTION
CONSULTATION WORKSHEET

Patient _____ Age _____ Sex _____
XRay # _____ Wt. _____ Ward _____
Physician _____ Pregnant? Yes No

TEST	RANGE	ISOTOPE	ISOTOPE ROUTE	PHARMACEUTICAL USUAL	Rx DOSE
☐ BONE SCAN	10-30mCi	TcHDP	I.V.	25 mCi	
☐ RENAL SCAN	3-15mCi	TcDTPA	I.V.	5 mCi	
☐ VENT LUNG	10-40mCi	Xe 133	Inh.	QS mCi	
☐ PERF LUNG	1-5mCi	TcMAA	I.V.	5 mCi	
☐ DISIDA SCAN	1-8mCi	TcDISIDA	I.V.	5 mCi	
☐ Ejection Fraction	0.02uam/Kg	Kinevac*	I.V.		
☐ THYROID S/U	100-400uCi	I 123	P.O.	250 uCi	
☐ LIVER/SPLEEN	1-8mCi	S.COLLOID	I.V.	5 mCi	
☐ GASTRIC EMPTY	450-550uCi	S. COLLOID	P.O.	500 uCi	
☐ MECKEL'S SCAN	10-15mCi	TcO4	I.V.	12.5 mCi	
☐ RBC GI BLEED	10-20mCi	ULTRATAG	I.V.	20 mCi	
☐ OTHER					

Approved: ☐ Yes ☐ No Radiologist: Date:

Apply Dose Sticker Here

Test Information:

Technologist _____ Time _____ Site/Route _____

Patient History:

Yes	No	IF Yes. Comments.....
☐ Pregnancy	☐	
☐ HTN	☐	
☐ Diabetes	☐	
☐ Cancer	☐	
☐ Prosthesis	☐	
☐ Lung Disease	☐	
☐ Liver Disease	☐	
☐ Heart Disease	☐	
☐ Recent Injury	☐	

Pertinent Medical History: _____

Meds/Labs _____

Previous Studies:

☐ Previous Scan
☐ Plain Films
☐ [illegible]

Supervising Radiologist:

Additional views _____
Correlative films _____
Physician _____ Date _____

Approved March 25, 1994

Ball Memorial Hospital
NRC License No. 13-00951-03 Renewal Request
November 1993

PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.6

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

   (1) Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.

   (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

   (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

   (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, packages are received at the Nuclear Medicine department.

4. If off duty deliveries are necessary, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.