**DEPARTMENT OF THE ARMY**
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920-5001

REPLY TO
ATTENTION OF

Radiation Protection
Officer



US Nuclear Regulatory Commission, Region IV
ATTN: Medical Licensing
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

RE: Change to Quality Management Program
License Number 42-05255-07

Dear Ms Burks,

The enclosed documentation denotes a recent change to William Beaumont Army Medical Center's Quality Management Program (QMP) concerning the record reviews we perform.

In addition to our annual QMP review we will also conduct a weekly and biannual review. We have discontinued our quarterly review requirement.

Please note that our QMP checklist is also changed. We are now ensuring that administered doses are within plus or minus ten percent of the dose prescribed on our written directives.

William Beaumont is fully committed in ensuring the safest hospital environment for our patients and employees. If we can be of any service or if your Agency has any questions, please contact our Radiation Protection Officer at (915) 568-7588.

Sincerely,

Theodore R. McNitt
Colonel, Medical Corps
Deputy Commander for
Clinical Services

Enclosure

200023

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ANNEX Z

WILLIAM BEAUMONT ARMY MEDICAL CENTER
QUALITY MANAGEMENT PROGRAM

1. PURPOSE: This policy is intended to comply with the requirements set forth in Title 10 Part 35.32 of the Code of Federal Regulations regarding the Quality Management Program. This program will be an integral part of the overall clinic Quality Assurance Plan and will be adhered to by all personnel working in the Nuclear Medicine Clinic.

2. PATIENT IDENTIFICATION: To ensure administration of prescribed radiopharmaceutical dosage to the proper patient, at least two of the following methods of identification will be required:

a. A valid Military identification card or any ID card with photograph.

b. Sponsor's/member's Social Security Number provided from memory (to be verified by medical card imprint)

c. For dependents under 10 years of age without an ID card, the parent or guardian of the minor will verify the child's identity . Parent/Guardian identification will be made by comparison with their identification card, as above.

d. Identification by comparison with an Inpatient (Hospital) ID bracelet.

e. For unconscious inpatients, patient identity will also be verified through hospital clinical staff corroboration.

3. CLINICAL REVIEW: No prescriptions will be signed by authorized users until review of the clinical data (on the consultation sheet and/or by conference with referring physicians) has been performed.

4. PRESCRIPTION ORDERS: Radiopharmaceuticals for both therapy doses and diagnostic doses of I-125 or 1-131 greater than 30 uCi will not be administered without a written prescription order. This written order will be for a specific patient and will contain the date of the order, radiopharmaceutical, dosage and signature of an authorized user at WBAMC. ALL therapeutic doses of radiopharmaceuticals will be verified in the dose calibrator by two individuals (normally a physician and the pharmacist or technologist who prepared the dose) prior to administration to the patient. Verification of the dosage will be documented by

initialing the actual dose on the label placed on the prescription form. The person administering the dose will indicate/verify that the dose was given by placing his/her initials and the time of administration on the prescription form.

a. Revisions to written prescriptions: Revision to a written directive must be dated and signed by an authorized user prior to administration of the dosage. An oral order may be used if the condition of the patient warrants an immediate change in a written order. If an oral revision to a written order is made, a revised written order will be placed in the patient record within 48 hours of the oral order.

b. Oral prescription orders: In emergency situations, an oral directive can be accepted if the condition of the patient is such that a delay of the order would be detrimental to the patient's health. The oral directive must be documented in the patients chart and a written directive will be placed in the patient's record within 24 hours.

5. UNINTENDED DEVIATIONS FROM WRITTEN DIRECTIVES:

a. In the event of an unintentional deviation from the written directive in the administration of a radiopharmaceutical, the following steps will be taken:

1. Insure the patient's safety.

2. Contact the Nuclear Medicine physician that prescribed the written order. He/she will evaluate the patient and give further instructions concerning the study.

3. Contact the RPO to report the incident. The RPO will determine if the deviation requires further action.

4. Contact the referring physician if the Nuclear Medicine physician feels it is necessary.

b. All Nuclear medicine personnel will attend periodic training concerning clinic procedures. This training will serve as an open forum for discussion about procedures and policies in an effort to have all personnel clearly understand clinic procedures. If any worker does not understand a procedure or written directive, that worker must seek guidance from the clinic NCOIC, technologist director, physician or radiopharmacist.

6. PREGNANCY STATEMENTS: Prior to administration of radiopharmaceuticals to female patients 12 to 50 years of age, a statement signed by the patient will be obtained attesting to the fact that there is no possibility that she may be pregnant. If even the slightest doubt concerning possible pregnancy exists, a negative Beta HCG test will be obtained within three (3) days prior the administration of the radiopharmaceutical. The only exception will be a medical determination that benefit from the study outweighs the risk of radiation exposure to the fetus.

7. THERAPY DOSES: Therapy doses of radiopharmaceuticals will not be administered without a written prescription order (written directive). The prescription will be written for a specific patient and will contain the date of the order, radiopharmaceutical, dosage and signature of an authorized user at WBAMC.

a. ALL therapeutic doses of radiopharmaceuticals will be verified in the dose calibrator by two individuals prior to patient administration. Verification of the dosage will be documented by initialing the actual dose on the label placed on the prescription form.

b. The person administering the dose will verify patient identity by at least two methods IAW paragraph 2 of this policy, placed his/her initials and write the time of administration on the prescription form.

c. The attached Quality Management Checklist will be completed prior to the administration of any therapeutic radiopharmaceutical. The completed checklist will be included in the Nuclear Medicine Patient record and will be utilized during the evaluation/review process.

d. Any unintended deviations from this procedure will be identified, evaluated and corrected in the manner specified in paragraph 5 of this policy.

8. COMPLIANCE: This policy will be reviewed by all radiation workers in the Nuclear Medicine Clinic at the inception of this program and annually thereafter. All new radiation workers assigned to this service will review this policy upon assignment for duty. Annual training in QMP procedures for Nuclear Medicine personnel will be conducted.

9. EVALUATION AND REVIEW:

a. Periodic reviews of the William Beaumont Army Medical Center Quality Management Program will be performed at intervals not to exceed twelve months to determine the effectiveness of the program. An annual review of the program will include an evaluation of a representative sample of patient administrations (not fewer than 10% of diagnostic doses and 100% of all therapy doses), all NRC recordable events, and NRC misadministrations. Patient records will be selected for review in a random manner. If during a review, a recordable event or misadministration is discovered, the sample size to be reviewed will increase to 25% of all diagnostic doses.

b. The annual review will be conducted by a "disinterested" party (someone other than the Clinic Chief, NCOIC or Radiopharmacist) to prevent a person from reviewing his/her own work. The review will be forwarded to the licensee for review and evaluation. The review will also be documented and made available for inspection.

c. In addition to the annual review, two clinic reviews will be accomplished to ensure quality patient care:

1) Weekly Review: All patients charts for one day of the week will be review by a staff physician, radiopharmacist and technical services technologist. The charts will be reviewed using the attached Nuclear Medicine Service Quality and Appropriateness of the Study checklist. Results of this review will be documented and evaluated for each staff physician, radiopharmacist and technologist.

2) Biannual Review: On a biannual basis the Chief, Nuclear Medicine Service will review those studies performed over half the year for study volume, proper radiopharmaceutical administration and a clinical aspect of care. This review is documented and forwarded to Chief, Department of Medicine.

d. As a result of the weekly, biannual and annual reviews, the QMP program will be modified as needed to increase the program's effectiveness. This evaluation of the program is an ongoing, dynamic evaluation to ensure quality care . The RPO, Chief of Nuclear Medicine, Clinic NCOIC and other individuals deemed necessary will evaluate the program and make recommendations for improvement. Any modifications to this program will be forwarded to the appropriate NRC Regional Office within 30 days after the modification has been made. Records of the annual review will be kept in an auditable form for three years and the weekly and biannual evaluation will be kept for 2 years. The annual evaluation/review will contain an evaluation of the relevant facts and what corrective action, if any, was taken.

e. Reviews of misadministrations or recordable events will be performed within 15 days of occurrence IAW 10 CFR 35.33

ALBERT MORENO
COL, MC
Chief, Nuclear Medicine Svc.

NUCLEAR MEDICINE
QUALITY MANAGEMENT CHECKLIST

Patient _____ Age _____
ID Number _____ Date of Therapy _____
Radiopharmaceutical _____ Dose _____

( ) 1. Patient disease appropriately documented.

( ) 2. Therapy dose prescription appropriately written.

( ) 3. Dose verified by TWO INDIVIDUALS prior to administration.

( ) 4. Dose within + / - 10% of that prescribed.

( ) 5. Patient identification verified by at least TWO METHODS

( ) 6. Negative B-HCG test documented on all female patients between 12 and 50 years of age.

( ) 7. Patient appropriately counseled and consent form complete:

( ) a. Risk of future cancers and genetic defects.

( ) b. Alternatives to therapy.

( ) c. Potential outcome of no therapy.

( ) d. Potential outcome of radiopharmaceutical therapy.

( ) e. Potential for retreatment.

( ) f. Avoidance of pregnancy.

( ) g. Avoidance of breast-feeding.

( ) h. Other potential problems noted as appropriate.

( ) 8. I-131 Therapy:

( ) a. Avoid personal contact with children for 3 to 4 days and intimate contact with spouse for at least 8 days for dosages less or equal to 15 mCi.

( ) b. Avoid personal contact with children for 5 to 7 days and intimate contact with spouse for at least 14 days for dosages greater than 15 mCi.

( ) c. No breast-feeding.

( ) d. Diet.

( ) e. Potential external contamination.

( ) 9. P-32 Therapy:

( ) a. Potential external contamination.

( ) b. Possibility of local tissue necrosis (not probable)

( ) 10. Sr-89 Therapy:

( ) a. CBC done prior to therapy (platelets >60,000 and WBC > 2400)

( ) b. Presence of bone metastasis confirmed prior to therapy.

( ) c. Temporary/transient increase in pain.

( ) d. Personal hygiene habits.

( ) e. Possible external contamination.

( ) 11. Complications appropriately noted and required follow-up completed.

ADDITIONAL COMMENTS:

**WILLIAM BEAUMONT ARMY MEDICAL CENTER**
**NUCLEAR MEDICINE SERVICE**
**QUALITY AND APPROPRIATENESS OF THE STUDY**
**AGREEMENT WITH INTERPRETATION**

Patient Name: _____

Patient Social Security Number: _____

Date of Procedure:_____ Type of Study:_____

Primary Physician Interpretor:_____

**Physician's Review** Date: _____

Unusual Occurences:

| | | |
|---|---|---|
| Patient distress during study | Yes | No |
| Infiltration of Isotope | Yes | No |
| Patient motion on scan | Yes | No |
| Patient failed to return for competion of study | Yes | No |
| Patient rescheduled | Yes | No |
| Other Unusual Occurences _____ | | |

| | | | |
|---|---|---|---|
| Isotope Dose Administered | Acceptable | Not Acceptable | |
| Accepted Indication for Study | Yes | No | |
| Technical Quality of Study | Yes | No | |
| Agreement with interpretation | Yes | No | Can not Determine |

Problems Identified in the Study _____

Name and Signature of Reviewer_____

**Pharmacy Review** Date: _____

| | | |
|---|---|---|
| Patient Identification Performed | Yes | No |
| Pregnancy statement fill and signed by patient | Yes | No |
| Prescription signed by authorized user | Yes | No |

| | | |
|---|---|---|
| Study explained to patient | Yes | No |
| Administration documented | Yes | No |
| Label contains the patient name, date, radiopharmaceutical and dose | Yes | No |
| Dose dispensed within 10% of prescribed dose | Yes | No |
| Prescription for I-131 and I-125 diagnostic and therapy over 30 uCi issue | Yes | No |

I-131 and I-125 diagnostic and therapy over 30 uCi prescriptions contains:

| | | |
|---|---|---|
| Patient name | Yes | No |
| Date | Yes | No |
| Radiopharmaceutical | Yes | No |
| Authorized user signature | Yes | No |

Therapy doses:

| | | |
|---|---|---|
| Verify in dose calibrator by two individuals whom initiated the label | Yes | No |
| Written consent form signed by the patient | Yes | No |
| Dose dispensed within +/- 10% of prescribed dose | Yes | No |
| Quality Management Checklist Completed | Yes | No |

Name and Signature of Reviewer _____

**Technical Services Review** Date: _____

| | | |
|---|---|---|
| Study performed/adquired IAW SOP's or written explanation of changes documented | Yes | No |
| Study computer processed IAW SOP or wirtten explanation of changes documented | Yes | No |

Images properly labeled with patient name, id, date, study, isotope, image view, Rt/Lt markers and any special necessary information Yes No

Study performed/processed/turned in for interpretation in timely manner Yes No

Comments:

Name and Signature of Reviewer _____