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U. S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Attn: Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

IR 2005001

Re: Notice of Violation: Docket # 03003308: License # 45-01589-01

Dear Ms. Henderson,

Included with this mailing is the supporting information that agent W. Lee asked for on 01/31/06 (SM-153 Policy).

Sincerely,



Dana W. Hare, RSO

kdc

TITLE	Palliative Bone Pain Therapy	CODE #	PC-WMC-NM 89
FACILITY	Winchester Medical Center	PAGE #	1 of 4
DEPARTMENT(S)	Nuclear Medicine		
EFFECTIVE DATE	08/05	FUNCTION	PC-Provision of Care, Treatment, and Services
REVIEWED	1/06	RESOURCE	Manager, Nuclear Medicine & PET Services
REVISED		SUBFOLDER	Nuclear Medicine
APPROVAL			
<u>SIGNATURE</u>	<u>TITLE</u>	<u>SIGNATURE</u>	<u>TITLE</u>
_____	NM Modality Section Leader	_____	Manager, Nuclear Medicine & PET
_____	Corp. Director, Medical Imaging	_____	Radiation Safety Officer

PURPOSE

To state the policy in evaluating patients who might be candidates for ¹⁵³Sm-lexidronam (¹⁵³Sm-EDTMP) radiopharmaceutical treatment of bone pain resulting from osteoblastic metastases, to provide information for performing this treatment, and to assist in understanding the sequelae of therapy.

STATEMENT OF POLICY AND PROCEDURE

I. INDICATIONS

- A. ¹⁵³Sm-lexidronam (¹⁵³Sm-EDTMP) is indicated for the palliation of intractable bone pain for patients with two or more osseous metastases (osteoblastic metastatic bone lesions) documented by bone scan from primary cancer.
- B. Candidates should have multiple bone metastases sites, bone pain, white blood cell (WBC) count of >2400, and a platelet count of >60,000. Other candidates are those who have failed hormonal therapy for prostate cancer management.
- C. Assessment of painful bone metastases for the use of palliation in conjunction with, or instead of, radiotherapy or chemotherapy.

II. CONTRAINDICATIONS AND PATIENT SELECTION

- A. Absolute Contraindications
 1. Pregnancy, breastfeeding or women of child-bearing age
 2. Acute or chronic renal failure (GFR less than 30 mL/min)
 3. Acute or impending spinal cord suppression or long bone fractures.
 4. Low hemoglobin (<90g per liter)
 5. Low white blood cell count (<3500)
 6. Low absolute neutrophil count (<1500)
 7. Low platelet count (<60,000)
 8. Patients with pain from other causes which mimics bone pain
 9. Patients receiving other phosphonate-based therapies within 2 to 3 days of treatment

- B. Situations that are **NOT** contraindications exist for the following:
1. Previous heavy external beam irradiation
 2. Previous failure of Bone pain therapy
 3. Anemia
 4. Conventional methods of pain palliation (e.g., analgesics, inflammatory drugs, hormonal therapy) that have not yet been used or are being used and have not yet failed.

III. SCHEDULING, DOSAGE AND PROCEDURE

- A. Patients are scheduled by the Nuclear Medicine Department.
1. The referring physician will complete the Samarium Therapy Eligibility Worksheet (Appendix 1) and fax to the Nuclear Medicine Department.
- B. To determine eligibility, a Nuclear Medicine Technologist who has received training and competency in Samarium Therapy's must complete the Eligibility worksheet, create a file for the patient and submit to the Authorized User for review.
1. The worksheet is given to a Radiologist who is an authorized user of Samarium.
 - a. If the patient is eligible, the Radiologist will sign the form and the patient may be scheduled for therapy.
 - b. Samarium therapy can only be performed on Wednesday, Thursday, or prior to 12 noon on Fridays due to radiopharmaceutical availability.
 - c. If the patient is not eligible the Radiologist will consult the referring physician and will note this in the patient's chart.
- C. The patient is then scheduled for an evaluation with the Radiologist.
1. The evaluation consists of a 30 minute visit in which the Radiologist verifies the eligibility, discusses the procedure, expected benefits and possible complications with the patient.
 2. If the patient agrees to have the therapy, the Radiologist will schedule the appointment and notify a technologist to order the radiopharmaceutical.
- D. The technologist will call the Radiopharmacy to order the prescribed amount of Samarium according to the written directive. The prescribed amount of ^{153}Sm -lexidronam (^{153}Sm -EDTMP) is 1mCi (millicurie) per Kg (kilogram).
- E. A Samarium chart is created for the patient and contains but is not limited to the following documents:
1. Informed Consent
 2. Pregnancy Form (if applicable)
 3. Radiologist Charge Sheet
 4. Lab Work
 5. Patient Instructions
 6. Patient Discharge Instructions
 7. Eligibility Worksheet
 8. Progress Record

IV. PATIENT PREPARATION

- A. Patients do not need to fast prior to administration of the radiopharmaceutical; however, they do need to be well hydrated 24 hours prior to and 24 hours following the administration of Samarium-153.
- B. The Radiologist will obtain written informed consent (Appendix 2).
- C. Hospitalization is usually not required for the administration of ^{153}Sm -lexidronam (^{153}Sm -EDTMP).

V. TECHNIQUE OF ADMINISTRATION

- A. A QMP Checklist form will be filled out (Appendix 3).
- B. The authorized technologist will verify the patients identity via 2 methods as described in the QMP checklist.
- C. A second technologist will verify the patient's identity in the same method and sign the QMP checklist.
- D. An IV will be inserted in the patient's vein (preferably the antecubital fossa), taped securely and flushed with 10 cc's of normal saline.
- E. Absorbent padding (Chux) is placed under the patient's arm where the IV site is located and on the floor below the injection area and/or any where that the possibility of contamination could occur.
- F. The written directive is verified by the administering technologist and the verifying technologist and noted on the QMP Checklist.
- G. The radiopharmaceutical is placed in the dose calibrator using the following setting: **SM153 Calibration number is 247**
- H. The administering technologist and the verifying technologist will assay the dose and record the lot number, calibrated activity, dose calibrator radiopharmaceutical setting, calibration setting, actual dose administered, route of administration, date and time administered, the signatures of the administrator, verifier, and the Radiologist as listed on the QMP checklist.
- I. The Radiologist (authorized user) will administer the ^{153}Sm -lexidronam (^{153}Sm -EDTMP) to the patient and sign the QMP form as the administrator.
- J. Upon completion of the injection, the technologist will remove the IV site from the patient.
- K. The IV, tubing and empty ^{153}Sm -lexidronam (^{153}Sm -EDTMP) syringe will then be assayed in the dose calibrator for residual activity and this will be recorded on the QMP Checklist as such.
- L. The residual activity is subtracted from the actual dose to obtain the administered dose.
 1. The administered dose is recorded in the NMIS (Nuclear Medicine Information System) as the dose the patient received.

VI. DISCHARGE INSTRUCTIONS

- A. A follow-up visit may be scheduled by the Radiologist per his discretion.
- B. A copy of the Samarium discharge instructions should be given to each patient (see Appendix 4).
- C. The patient is given instruction on current issues regarding the triggering of radiation monitors in public transportation facilities. The patient is asked to sign a consent form authorizing Winchester Medical Center to release information concerning the patient's examination, if need, to security or law enforcement personnel (Appendix 5).
 1. After the patient signs the consent form, they are issued a card to carry with them that contains information concerning the procedure performed, the date of the procedure, and half-life of the isotope utilized for the procedure.
- D. After the patient is removed from the injection room, the absorbent material will be surveyed with a GM survey meter to assess if any contamination occurred.

1. If **no contamination** is evidenced, the absorbent material will be disposed in the regular trash.
2. If there is **evidence of contamination**, the spill procedure will be initiated and the Radiation Safety Officer contacted.