Saint Margaret Mercy
Healthcare Centers

NORTH CAMPUS ▫ 5454 Hohman Ave., Hammond, IN 46320 Phone: 219/932-2300 ▫ 708/891-9305
SOUTH CAMPUS ▫ U.S. Highway 30, Dyer, IN 46311 Phone: 219/865-2141 ▫ 708/895-1650

December 13, 1993

U.S. Nuclear Regulatory Commission
Region III
Attn: B.J. Holt, Chief
Nuclear Materials Inspection
Section I
799 Roosevelt Road
Glen Ellyn, IL 60137

License No. 13-02047-02
Docket No. 030-01602

Dear Mr. Holt:

This letter is in response to your report, dated December 1st, 1993, to Sister Corita Last, Vice President for Clinical Support Services, regarding the NRC inspection of our licensed activities by Mr. James Mullauer and Mr. Kevin Null on June 29, 1993.

Your report indicates that we did not comply to current NRC regulations in two respects:

1) No QM procedure for the administration of I-131 in quantities greater than 30 μCi was included in our quality management program submitted to your office on December 27, 1991, nor was it submitted at a later date.

2) A written directive for the administration of 5.6 mCi of I-131 on June 11, 1993 was not dated by the authorized user, and this omission was not noted during a quarterly review.

Response:

1) In December 1991, when we submitted our quality management program to your office, we neither performed nor planned to perform I-131 administrations in quantities greater than 30 μCi. Therefore no QM procedure was in place at that time. The Radiation Safety Officer called your office in 1992 to inquire about the adequacy of our QM program. The answer was that these programs would be reviewed at a later time. Until then, no further action seemed necessary.

The first I-131 administration (>30 μCi) was performed in July, 1992. A copy of the relevant QM procedure was given to your inspectors during their visit on June 29, 1993.

Since your visit, we have started to use Sr-89 chloride for pain palliation. We have therefore updated our QM procedure to include Sr-89. We also wrote new procedures for the dose assay and the administration of Sr-89 chloride. Please find enclosed a copy of our updated QM procedure as well as the new Sr-89 procedures. We request that these be incorporated into your files of our quality management program.

2) The enclosed QM procedure states that a written directive must be signed and dated by the medical director or alternative (who must be an authorized user) prior to the administration of the radiopharmaceutical.

In addition, we have instituted the following review process of each I-131 administration (>30 μCi) as well as of each Sr-89 administration:

The Radiation Safety Officer will review all written directives at the quarterly isotope meeting and record his/her findings on the attached form. These forms will be kept in the RSO office and are available for your inspection.

It is our understanding that the actions outlined above will place us in full compliance with current NRC regulations. Please feel free to call me at (219) 933-2130 should you need further information.

Sincerely,

R. Muller-Runkel, Ph.D.
Radiation Safety Officer

cc: Sister Corita Last
Dr. U. Kalokhe
Dr. T. C. Wang
Marla Hoyer-Lareau

RMR/dt

Saint Margaret Mercy Healthcare Centers

Subject: Quality-QM/Use of Sodium I-131, I-125 or Sr-89

Policy # 7241-016

Responsible Department/Division Nuclear Medicine/Radiation Oncology

___Administrative _X_ Policy Reviewed Date_____

___Medical Staff _X_ Procedure _____

___Divisional _X_ Original Date 12/10/91 _____

_X_ Departmental _X_ Supersede Date 6/29/93 Revised Date 9/21/93

Responsible Personnel MD,NM,RS

PURPOSE: To inform the Nuclear Medicine Technologists, Physician, or Brachytherapy nurse of the requirements for the administration of radioactive sodium iodine or strontium-89 for quantities greater than 30 uCi.

STATEMENT OF POLICY:

1.0 A written directive must be obtained prior to the administration of quantities greater than 30 uCi of Sodium I^{131} , I^{125} or Sr^{89}.

2.0 Prior to the administration of the radioactive drug the patient's identity is verified by more than one method.

3.0 All administrations of this category are to be recorded and placed in the log book.

4.0 Srontium-89 injections must be performed by the authorized user on the NRC license.

PROCEDURE:

1.0 All physician orders which involve the usage of sodium I^{131} , I^{125} or Sr^{89} in quantities greater than 30 uCi must be reviewed by the appropriate medical director or alternate (who must be an authorized user).

2.0 The medical director or alternate must prepare a written directive which is an order in writing for the specific patient; it must be dated and signed prior to the administration of the radiopharmaceutical. The term "microcurie" or "millicurie" must be written out in full.

Policy # 7241-016

Subject: Quality-QM/Use of Sodium I-131, I-125 or Strontium-89

3.0 A technologist or physician shall order the radiopharmaceutical from the radiopharmacy or supplier.

4.0 Prior to each administration, the patient's identity must be verified by:

4.1 For out-patients, ask the patients name and verify this against identification that they must bring with them such as a driver's license.

4.2 For in-patients, ask the patients name and compare this with corresponding information in the patients medical record and check the hospital ID bracelet.

5.0 Prior to the administration verify that the dosage as determined from the assay in the dose calibrator is in accordance with the written directive.

6.0 Record all information as indicated on Attachment I.

7.0 If the dosage of NaI^{131} is 30 millicuries or greater follow the procedure stated in the policy "Use of Radioactive I^{131} for Thyroid Therapy".

APPROVALS: Radiation Safety Committee 9/93

SIGNATURES:

Medical Director — Date 11/93

Divisional Vice President — Date 11/93

Radiation Safety Officer — Date 11-8-93

Director — Date 11/93

Manager — Date 11/93

Policy # 7241-016

Subject: Quality-QM/Use of Sodium I-131, I-125 or Strontium-89

Lead Technologist Date

[signature] 11/93

Chief Nuclear Medicine Technologist Date

SAINT MARGARET MERCY HEALTHCARE CENTERS

Written Directive for Therapy/Treatment Doses

This section to be completed by an authorized NRC user

Patient Name: _____

Medical Record #: _____

Referring Physician: _____

Diagnosis: _____

Reason for Procedure: _____

Radioisotope & Activity Requested: _____
(Specify "millicurie" or "microcurie")

Requested By: _____
(signature of requesting NRC user)

Date Requested: _____

Administrative Log Sheet

Date Dose Ordered: _____

Dose Ordered By: _____

Date Dose Recieved: _____

Date of Procedure: _____

Method Used To Verify
Patient's Identity: _____

Route or Site of Adminstration: _____

Dosage Administered: _____

Lot#: _____

Administered By: _____
(Signature of Authorized User)

Technologist: _____

SAINT MARGARET MERCY HEALTHCARE CENTERS

Subject: ADMINISTRATION OF STRONTIUM-89 CHLORIDE Policy # 724-101

Responsible Department/Division NUCLEAR MEDICINE/RADIATION ONCOLOGY

___ Administrative	X Policy	Reviewed Date ___
X Medical Staff	X Procedure	___
___ Divisional	X Original Date 10/1/93	___
X Departmental	___ Supersede Date NEW	Revised Date ___

PURPOSE:

Strontium 89 is a beta particle emitting radionuclide which localizes in the bone. It is indicated for palliative relief of bone pain associated with widespread metastatic involvement (blastic lesions).

1.0 Strontium 89 (Sr 89) chloride injection will be dispensed through the Nuclear Medicine Department.

2.0 Strontium 89 may only be administered under the orders of an Oncologist, who is a member of the Internal Medicine Department.

3.0 The indication for Sr 89 administration is bone pain with widespread metastatic involvement.
- 3.1 Patients must have documented primary carcinoma with painful and widespread metastatic bony lesions as evidenced on a bone scan.
- 3.2 Patients must have severe bone pain with increasing requirements for pain medication and have not responded to conventional therapy.

4.0 Strontium 89 is contraindicated in patients with:
- 4.1 Evidence of seriously compromised bone marrow from previous therapy or disease infiltration.
- 4.2 A very short life expectancy due to the delayed onset of pain relief, typically 7 - 20 days post injection.
- 4.3 Cancer not involving bony metastases.

5.0 Strontium 89 should be used with caution in patients with:
- 5.1 Platelet count below 60,000/mm3
- 5.2 Leukocyte count below 2,400/mm3
- 5.3 Hematocrit below 15%
- 5.4 Serum creatinine above 4.0 mg/dl

6.0 The minimum evaluation necessary before administration should include:
- 6.1 History
- 6.2 Pain evaluation
- 6.3 Bone scan
- 6.4 Serum creatinine
- 6.5 CBC within 72 hours prior to administration.
- 6.6 A pregnancy test is required of females of child bearing age who have not undergone a sterilization procedure.

7.0 Administration of Strontium 89
- 7.1 A consent of a radionuclide administration is required and a written (Directive) prescription for the Strontium 89 must be received.
- 7.2 Verification of dose and patient identification must be obtained prior to administration due to its relatively high level of radioactivity.
- 7.3 It must be administered by a qualified physician who is authorized user on the Nuclear Regulatory Commission (NRC) hospital license or his/her physician designee.
- 7.4 There is no special preparation prior to injection.
  - 7.4.1 Injection must be prepared from the same drug lot for a particular patient. Strontium 89 from different lot numbers cannot be mixed.
  - 7.4.2 Administration via a venous access device or rubber hub of an IV line is not recommended.
  - 7.4.3 Administration via a scalp vein with a 3-way stop cock is recommended with normal saline pre and post flush.
  - 7.4.4 It should be administered by slow intravenous injection over 1-2 minutes.
  - 7.4.5 A calcium-like flushing has been observed in patients following rapid (less than 30 second) administration.
- 7.5 It is recommended that the radionuclide be stored inside its transportation container until administered.
- 7.6 Disposal of used equipment should be per hospital policy.
- 7.7 Document pertinent information on the flow sheet (see attached).
- 7.8 Repeated administration of Strontium 89 should be based on:
  - 7.8.1 Individual's response to therapy.
  - 7.8.2 Current symptoms.
  - 7.8.3 Hematologic status.
- 7.9 Repeated administration is not recommended at intervals of less than 90 days.

8.0 COMPLICATIONS

8.1 Bone marrow toxicity is to be expected following administration particularly with leukocytes and platelet.

8.1.1 Blood counts should be monitored at least every two weeks.

8.1.2 Nadir in most patients is found between 12-16 weeks post administration.

8.1.3 Results of blood counts and palliative intent will be followed by the oncologist.

8.2 To minimize the risk of radioactive contamination of clothing, bed linen and the patient environment, special precautions, e.g. urinary catherization of an incontinent patient, should be taken prior to administration and remain in effect for 48 hours.

Administrative Directors	Date 10/25/93 10/27/93	Medical Director Nuclear Medicine	Date 10/27/93
Divisional Vice Presidents	Date 10/93	Medical Director Radiation Oncology	Date 10/25/93

11-18-93

Radiation Safety Officer

Saint Margaret Mercy Healthcare Centers

Subject: Dose Assay of Metastron Strontium-89

Policy # 7241-017

Responsible Department/Division Nuclear Medicine/Radiation Oncology

___Administrative ___Policy Revi:wed Date_____

___Medical Staff _X_Procedure _____

___Divisional _X_Original Date 9/21/93 _____

_X_Departmental ___Supersede Date_____ Revised Date_____

Responsible Personnel MD,NM,RS,RO

PURPOSE: To provide a safe and consistent method of assaying individual Metastron Sr-89 doses for patient injection.

STATEMENT OF POLICY:

1.0 When supplied, Metastron has a radioactive concentration of 37 MBq/ml, 1 mCi/ml at 0600 CST on its calibration date which is stated on the shipping vial label. The label also states the total activity (148 MBq, 4 mCi) in the vial on the calibration date and the volume of solution (4 ml) in the vial. Both the radioactive concentration and the activity are determined by liquid scintillation techniques traceable to the National Institute of Standards and Technology (NIST). This traceability has been established by both Amersham and NIST performing assays on the same Sr-89 sample and achieving agreement to within 1.5%.

2.0 First Shipment Vial:

2.1 Upon receipt of Metastron consult the decay chart in the package insert (see Table 1 below) and determine the total activity in the vial. (For example, if the calibration date is February 24th then the total activity at 0600 CST on February 14th will be 1.15 x 148 MBq, i.e. 170.2 MBq, [1.15 x 4 mCi, i.e. 4.6 mCi]).

2.2 Place the vial in the dose calibrator and adjust the potentiometer setting until the electrometer reads the same activity as you just calculated. This potentiometer setting is then the Sr-89 setting for the particular dose

calibrator being used. Make a record of the setting.

2.3 North Campus Dose Calibrator Usage:

2.3.1 Enter the Sr^{89} as standard into the inventory. After completing all the necessary information for the inventory addition, with the display in the zero state, enter the inventory name on the second line if it is not already present (STD SR89).

2.3.2 Press the CALIB key. The display will show:

```
PLACE SAMPLE IN WELL
PRESS ENTER TO MEASURE
```

Place the Metastron vial in the dose calibrator well and press the ENTER key.

2.3.3 After pressing the ENTER key, the display will show:

```
STD. SR-89    89 SR     4 MCI
MEASUREMENT IN PROGRESS .....
```

2.3.4 When the measurement is complete, the display will show:

```
REPLACE CF WITH THE NEW ONE (Y/N)
NEW CR = ........ OLD CF = 176
```

The new CF has been calculated based on the decay corrected activity from the inventory and the measured sensor current. Press the Y key to replace the old CF. The new CF will b used for each subsequent dose measurement of Sr^{89}.

2.4 South Campus Dose Calibrator Usage:

Follow 2.1 and 2.2.

3.0 After determining the total activity in the shipping vial draw the required dose into the syringe.

3.1 Reassay the shipping vial to determine the activity remaining in the vial and then the activity in the syringe is given by subtracting this activity from the original activity in the shipping vial.

4.0 First Shipment in Syringe (Alternate Method):

4.1 In this case the radioactive concentration (mCi/ml) should first be determined from the decay chart in the package insert. (For example, if the calibration date is February 24th then the radioactive concentration at 0600 CST on February 14th will be 1.15 x 37 MBq/ml, i.e. 42.55 MBq/ml, [1.15 x 1 mCi/ml, i.e. 1.15 mCi/ml].)

4.2 This concentration should then be multiplied by the volume of Metastron drawn into the syringe to give the total activity in the syringe.

4.3 The syringe is then placed in the dose calibrator and the same procedure as that outlined above for the shipping vial is followed to establish a "Sr-89 syringe" setting.

4.3.1 Please note the setting for the syringe is likely to be different from the setting for the shipping vial. Additionally, the setting for one type of syringe may be different from the setting for a different type of syringe and it is advised, therefore, that a setting is established for each type/size of syringe used for Metastron.

5.0 Subsequent Shipments:

5.1 For subsequent vials/syringes of Metastron dial in the appropriate Sr-89 potentiometer setting as previously established by the methods outlined above.

5.2 Place the vial/syringe in the dose calibrator and measure the activity.

Policy # 7241-017

Subject: Dose Assay of Metastron Strontium-89

5.3 Consult the label and the decay chart in the package insert and determine the expected activity in the vial/syringe to confirm agreement.

5.4 Final assay reading must agree within 10% of the written directive.

SIGNATURES:

Medical Director — 11/93 Date

Divisional Vice President — 11/93 Date

Radiation Safety Officer — 11-8-93 Date

Director — 11/93 Date

Manager — 11/93 Date

Lead Technologist — Date

Chief Nuclear Medicine Technologist — 11/94 Date

Table 1: Decay of Strontium-89

Day*	Factor	Day*	Factor
-24	1.39	+6	0.93
-22	1.35	+8	0.90
-20	1.32	+10	0.87
-18	1.28	+12	0.85
-16	1.25	+14	0.83
-14	1.21	+16	0.80
-12	1.18	+18	0.78
-10	1.15	+20	0.76
-8	1.12	+22	0.74
-6	1.09	+24	0.72
-4	1.06	+26	0.70
-2	1.03	+28	0.68
0=calibration	1.00		

* Days before (-) or after (+) the calibration date stated on the vial.

If further information is required concerning the calibration of Metastron please call 1-800-554-0157.

(Please note: the above information is provided for guidance only. It does not supersede NRC or individual Agreement State requirements for the calibration of therapeutic radiopharmaceuticals. Individual establishments should confirm that the calibration procedures adopted conform to the appropriate NRC/State regulations.)

SAINT MARGARET MERCY HEALTHCARE CENTERS

Written Directive for Therapy/Treatment Doses

This section to be completed by an authorized NRC user

Patient Name: _____

Medical Record #: _____

Referring Physician: _____

Diagnosis: _____

Reason For Procedure: _____

Radioisotope & Activity Requested: _____
(Specify "millicurie" or "microcurie")

Requested By: _____
(signature of requesting NRC user)

Date Requested: _____

Administrative Log Sheet

Date Dose Ordered: _____

Dose Ordered By: _____

Date Dose Received: _____

Date of Procedure: _____

Method Used To Verify
Patient's Identity: _____

Route or Site of Administration: _____

Dosage Administered: _____

Lot#: _____

Administered By: _____
(Signature of Authorized User)

Technologist: _____

QUALITY ASSURANCE FORM FOR THERAPEUTIC ADMINISTRATIONS AND SODIUM IODIDE I-125 OR I-131 or Sr-89 DOSES ABOVE 30 MICROCURIES

This survey is to ensure that all requirements of the Nuclear Medicine Quality Management Program are followed and to evaluate the Quality Management Program.

PATIENT NAME: _____

NAME OF THERAPY OR RADIOIODINE PROCEDURE ORDERED:

_____ DATE: _____

A. Written Directive Present: Circle One YES NO

B. Patient Identification By Name: Circle One YES NO

C. Comparison Identification: Circle One

1. Birth Date 2. Address 3. Social Security Number
4. Signature 5. Bracelet 6. Hospital ID Card
7. Insurance Card 8. Driver's License

D. Dosage Within 20% of Written Directive: Circle One

YES NO If No Explain _____

E. Dose Administered _____ I-125 _____ I-131

_____ Other _____

F. Route of Administration _____

G. Was There Any Deviation From the Written Directive. Circle One

YES NO If Yes Explain _____

Form Completed BY: _____ Date: _____
Sign and Print Last Name

Saint Margaret Mercy
Healthcare Centers

NORTH CAMPUS ▫
SOUTH CAMPUS ▫

5454 Hohman Ave., Hammond, IN 46320 Phone: 219/932-2400 ▫ 708/891-9305
U.S. Highway 30, Dyer, IN 46311 Phone: 219/865-2141 ▫ 708/895-1650

To: B. J. Holt, NRC Region III

From: R. Muller-Runkel

Re: QMP (as per your phone request)

AINT MARGARET MERCY HEALTHCARE CENTERS

Subject: Quality-QM/Use of Sodium I-131,I-125, or Sr-89 Policy # 724N-016

Responsible Department/Division Nuclear Medicine/Radiatin Oncology

___Administrative	X Policy	Reviewed Date_____
___Medical Staff	X Procedure	_____
___Divisional	X Original Date 12/10/91	_____
X Departmental	X Supersede Date 8/93	Revised Date 1/94

PURPOSE: To inform the Nuclear Medicine Technologists or Brachytherapy nurse of the requirements for the administration of Sr^{89} or radioactive sodium iodine for quantities greater than 30 uCi.

'ATEMENT OF POLICY:

1.0 A written directive must be obtained prior to the administration of Sr^{89} or of quantities greater than 30 uCi of Sodium I^{131} or I^{125}.

2.0 Prior to the administration of the radioactive drug the patient's identity is verified by more than one method.

3.0 All administrations of this category are to be recorded and placed in the log book.

4.0 Sr^{89} injections must be performed by the authorized user.

PROCEDURE:

1.0 All physician orders which involve the usage of Sr^{89} or of sodium I^{131} or I^{125} in quantities greater than 30 uCi must be reviewed by the appropriate medical director or alternate (who must be an authorized user).

2.0 The medical director or alternate must prepare a written directive which is an order in writing for the specific patient; it must be dated and signed prior to the administration of the radiopharmaceutical. The term "microcurie" or "millicurie" must be written out in full.

Policy # 7241-016

Subject: Quality-QM/Use of Sodium I-131, I-125 or Strontium-89

3.0 A technologist or physician shall order the radiopharmaceutical from the radiopharmacy or supplier.

4.0 Prior to each administration, the patient's identity must be verified by:

4.1 For out-patients, ask the patients name and verify this against identification that they must bring with them such as a driver's license.

4.2 For in-patients, ask the patients name and compare this with corresponding information in the patients medical record and check the hospital ID bracelet.

5.0 Prior to the administration verify that the dosage as determined from the assay in the dose calibrator is in accordance with the written directive.

6.0 Record all information as indicated on Attachment I.

7.0 If the dosage of NaI^{131} is 30 millicuries or greater follow the procedure stated in the policy "Use of Radioactive I^{131} for Thyroid Therapy".

APPROVALS: Radiation Safety Committee 9/93

SIGNATURES:

Medical Director — Date 11/93

Divisional Vice President — Date 11/93

Radiation Safety Officer — Date 4-8-93

Director — Date 11/93

Manager — Date 11/93