UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

MAY 10 1994

Docket: 030-32211
License: 11-27371-01

Saint Joseph Regional Medical Center
ATTN: Howard Hays, Administrator
415 Sixth Street
Lewiston, Idaho 83501

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-32211/94-01

Thank you for your letter of April 26, 1994, in response to our letter and Notice of Violation dated April 8, 1994. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Sincerely,

Charles L. Cain

Charles L. Cain, Chief
Nuclear Materials Inspection Branch

cc:
Idaho Radiation Control Program Director

IE07

bcc w/copy of licensee letter:
DMB - Original (IE-07)
LJCallan
SJCollins
RAScarano, DRSS/RIV
DDChamberlain
DWeiss, OC/LFDCB (4503)
WLFisher
CLCain
RABrown
NMIB
RIV Files (2)
SLMerchant, NMSS/IMAB (6 H3)

RIV:NMIB	C:NMIB			
RABrown	CLCain			
05/10/94	05/10/94			

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RIV:NMIB	C:NMIB			
RABrown	CLCain			
05/10/94	05/10/94			

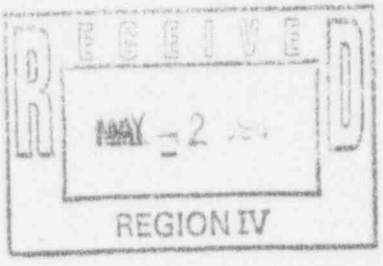
St. Joseph
Regional Medical Center
People committed to life

415 6th Street P.O. Box 816 Lewiston, Idaho 83501
Phone (208) 743 2511

26 April 1994

Dkt: 030-32211
Lic: 11-27371-01

REPLY TO A NOTICE OF VIOLATION



Regional Administrator
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Dear Sir or Madam,

This is a letter in response to a Notice of Violation following an inspection of our facility by Mr. Robert A. Brown on March 16, 1994. The particular violation cited by Mr. Brown involved a failure to submit a modification to our Brachytherapy Quality Management Program (QMP) made on July 31, 1993 and an addition to our QMP on November 5, 1993 to include the therapeutic administration of Metastron (Strontium-89) as required by 10 CFR 35.32(e).

The Brachytherapy QMP was updated by me to a) specifically include, by name, myself and Kent Anderson, M.D. in the QMP and b) to more closely follow the format recommended by the NRC. The Metastron addition to the QMP was added by me for obvious reasons - I wanted to have a written code of practice for the administration of Metastron. At the times I made the amendments to the QMP, I was a newly appointed hospital RSO (July 1, 1993) and I was unaware that I needed to send a copy of these amendments to the NRC, although it is obvious to me now that I should have done so.

I have enclosed for your perusal one copy each of the brachytherapy and Metastron QMP amendments. I had previously faxed copies of both to Robert Brown per his request shortly following his inspection visit.

In the future, I will promptly mail any QMP changes or additions to the NRC regional office. I have also asked the Director of Radiology to inform me when any changes or additions to the Nuclear Medicine QM program are made so that we can submit those changes to the NRC as well.

94-0869

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I trust that this letter and the enclosed copies of amendments will fully address the violation and demonstrate our full compliance. If you require further information or clarification, I can be contacted during working hours at (208) 799-5600.

Sincerely,

Douglas Heidorn

Douglas Heidorn, Ph.D.

cc: U.S. NRC Document Control Desk, Washington D.C.
Idaho Radiation Control Program Director
Howard Hayes, CEO, SJRMC
Bob Jones, Director of Radiology, SJRMC

Enclosures

St. Joseph's Regional Medical Center
Department of Radiation Oncology

BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

I. INTRODUCTION

A written quality management program is required by Federal Regulation 10CFR35.32 to "provide high confidence that byproduct material or radiation from byproduct material will be administered by the authorized user." All of the regulation requirements shall be met by implementing the instructions contained in this document.

Program approved by:

Kent Anderson, M.D. — 7/31/92 Date
Medical Director
Dept. of Radiation Oncology

Douglas Heidorn, Ph.D. — 7/31/92 Date
Medical Physicist
Dept. of Radiation Oncology

II. RESPONSIBILITY AND AUTHORITY OF PROGRAM

The responsibility and authority for maintaining the quality management program has been assigned to the Medical Physicist, Douglas Heidorn, Ph.D.

III. POLICIES AND PROCEDURES

A. Written Directive

10CFR35.32(a)(1) requires a written directive for any brachytherapy Radiation dose. As defined by 10CFR35.2, a "written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

For all other brachytherapy (other than HDR remote afterloading:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site and total source strength and exposure time (or, equivalently, the total dose)."

SJRMC Procedure #1

For every Brachytherapy implant, the following information on the Brachytherapy Prescription and Source Arrangement Sheet

must be filled out and signed by the physician before the sources may be implanted:

Patient information (including patient name and diagnosis & treatment site), radioisotope, implant/source configuration (including number of sources, activity of each source, total activity of implant and total number of sources), Dr. Anderson's signature and date.

After the sources have been implanted but prior to completion of the procedure, the following information must be supplied on the Brachytherapy Prescription and Source Arrangement Sheet:

Total dose to specific point of interest or isodose line, planned treatment time, actual date and time of implant insertion, physicians signature and date.

The radioisotope, treatment site, and total source strength will already be contained on the sheet. If changes need to be made, they should be clearly written and signed by Dr. Anderson.

B. Patient Identification: Prior to each brachytherapy administration, the patient's identity shall be verified by more than one method as the individual named in the written directive.

SJRMC Procedure #2

Prior to inserting the implant device (Tandem/ovoids, Syed template) in the operating room , Dr. Anderson will identify the patient by verbal communication and will confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, name on the patient's ID bracelet, name on the patient's hospital card or photograph of the patient's face.

C. Treatment Plan Checks: The final treatment plan and related brachytherapy calculations are verified to agree with the written directive.

SJRMC Procedure #3

The computer-generated treatment plan will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations, specifically the correct number, type and strength of sources.Drs. Anderson and Heidorn also confirm that the plan agrees with the written directive in regard to dose administered to relevant dose points.

D. Other Verification Checks: Each administration is verified to be in agreement with the written directive.

SJRMC Procedure #4: Verification that the brachytherapy administration is in agreement with the written directive requires three separate steps:

1) Both Drs. Anderson and Heidorn visually verify that the radioisotope, number of sources, source strength and loading sequence are in agreement with the written directive and treatment plan prior to implanting radioactive sources.
Cesium-137 Implants: Cesium sources are kept in a locked, shielded safe in a locked, shielded source room on the fourth floor of the hospital. The keys to the room and the safe are kept in the physicist's desk. There are 14 sources in the safe, the source position and strength is indicated on the front of the safe door. The sources are color coded according to strength using a color coding scheme. The color code is posted on the source room wall.
Iridium-192 Implants: Iridium sources are ordered from Best Products since they are not kept as part of the SJRMC permanent inventory. Source activities are not assayed by the physicist since the department does not have a dose calibrator; the manufacturer's specified nominal source activities are used in the treatment plan for dose calculations. Each ribbon is removed from the lead pig by Dr. Heidorn to check the number of seeds per ribbon. In the case where some ribbons have been ordered to contain more/fewer or higher/lower activity sources, these ribbons can be clearly marked by the physicist at that time.

2) Orthogonal radiographs are taken of dummy sources in the fixed-geometry template or treatment device in order to determine the exact location of the sources relative to the patient anatomy. the films are used to localize the sources by digitization using the treatment planning computer. The planning computer can then calculate the isodose curves of the actual sources.

3) If the loading is accomplished per the implant/source configuration information listed on the Brachytherapy Prescription and Source Arrangement form, then no further remarks need to be made. If there is a change in the loading, such change should be clearly noted and signed by Dr. Anderson.

E. Unintended deviations from the written directive: Any unintended deviations from the written directive need to be identified and appropriate action taken. 10CFR35.32(c) discusses steps that need to be taken to deal with recordable events and sections (a) and (b) discuss steps that need to be taken to deal with a misadministration. The definitions of both these terms are listed in 10CRF35.2.

SJRMC Procedure #5 Procedures to identify and evaluate any unintended deviations from the written directive will include the following:

1) The prescription instructions (total dose, implant time, source strengths and source arrangement) in the written directive are compared with the computer printout to make sure they agree.

2) When the sources are removed, the date and the time of removal will be noted in the Brachytherapy Prescription form and the total treatment time will be calculated. If the total treatment time is not within 1 hour of the planned treatment time, the form will be updated to reflect the actual treatment time. The reasons for any deviation will be addressed on that form and signed by Dr. Anderson.

If the change in total dose from the prescribed dose is large enough to qualify as a recordable event or misadministration, the following steps will be followed:

3) When deviations from the written directive are identified as recordable events:

a) Dr. Heidorn will assemble the relevant facts including the cause for the recordable event.
b) Corrective action will be taken to prevent recurrence.
c) A report containing the relevant facts and corrective action will be written and kept for a period of 3 years. The incident will be discussed among Drs. Heidorn and Anderson and all other personnel involved.

4) When deviations from the written directive are identified as misadministrations:

a) Dr. Heidorn will notify by telephone the NRC Operations Center no later than the next working day after the misadministration is discovered.
b) Dr. Heidorn will assemble relevant facts concerning the misadministration and corrective action will be taken.
c) A written report will be submitted to the NRC Regional Office within 15 days after the discovery of the misadministration. The report will contain all the items listed in 10CFR35.33(a)(2).
d) The requirements of 10CFR35.33(a)(3) and (4) will be followed with respect to notifying the referring physician and the patient.
e) The record of the misadministration will be maintained for 5 years as outlined in 10CFR35.33(b).

F. Maintaining Written Directives in Auditable Form: A written record of each written directive and a record of each administered dose shall be kept for 3 years after the date of the administration.

SJRMC Brachytherapy Procedure #6

Each written directive and record of administered dose is kept

in the patient's chart. A list of each implant patient and the date of implant is kept in the Source Log Book located in the source room.

III. AUDIT PROGRAM

SJRMC Brachytherapy Audit Sampling Policy

1) Following completion of each brachytherapy implant there will be a complete audit by Dr. Heidorn of the patient, implant and source information as described in the policies and procedures section of the Brachytherapy Quality Management Program.

2) On a quarterly basis, the Radiation Safety Committee will review all treatment aspects of each implant patient for that quarter. At that time, evaluations of the efficacy of the QM Program will be made.

SJRMC Audit Documentation

1) Dr. Heidorn will evaluate each implant for misadministration or recordable event. He will be responsible for ensuring that the proper action is taken should an implant qualify as either one of these events.

2) Each quarterly review by the RSC will be documented by the Administration Secretary in the form of meeting minutes. Any changes made to the Radiation Oncology Brachytherapy QM Policy by the committee will be documented in said minutes and will be implemented by Dr. Heidorn.

3) The department will retain records of each review, including the evaluations and findings of the review, in auditable form for 3 years.

St. Joseph's Regional Medical Center
Department of Radiation Oncology

RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM - METASTRON

I. INTRODUCTION

A written quality management program is required by Federal Regulation 10CFR35.32 to "provide high confidence that byproduct material or radiation from byproduct material will be administered by the authorized user." All of the regulation requirements shall be met by implementing the instructions contained in this document.

II. POLICIES AND PROCEDURES

A. Written Directive
As defined by 10CFR35.2, a written directive means "an order in writing for a specific patient, dated and signed by an authorized user prior to administration of radiation or a radiopharmaceutical."

SJRMC Procedure #1

Dr. Kent Anderson is the sole authorized user for Metastron (Strontium-89 Chloride, designated as a "New Drug Application" (NDA) by the FDA) and will provide a written directive for each patient that will include the following information:

1) Patient name and date
2) Radiopharmaceutical (Metastron)
3) Activity (Typically 4 mCi or 50 uCi/kg body weight)

B. Patient Identification: Prior to each Metastron administration, the patient's identity shall be verified by more than one method as the individual named in the written directive.

SJRMC Procedure #2

Prior to Metastron injection, Dr. Anderson will identify the patient by verbal communication and will confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, name on the patient's hospital card or photograph of the patient's face. The injections will take place in the designated Injection Room of the Nuclear Medicine Department and Dr. Anderson will coordinate patient scheduling with Nuclear Medicine and will be present for all administrations.

C. Activity Assay: Prior to injection, the activity of the Metastron injection shall be determined by Nuclear Medicine

personnel (Tom Rogers and/or Mary Harlow) per shipment protocol provided by Amersham.

SJRMC Procedure #3

Please see attached sheet "Guidelines for the Calibration of Metastron." The Metastron to be injected will be drawn into a syringe and the Metastron activity will be checked with Dr. Anderson's written directive.

D. Administration of Radiopharmaceutical

SJRMC Procedure #4

Nuclear Medicine personnel will administer Metastron injections per established procedures (see attached sheet and Nuclear Medicine Procedures for the Safe Use of Radiopharmaceuticals per 10CFR35.310). All Metastron injections will be administered using a labelled, shielded syringe.

E. Patient Discharge and Follow-up

SJRMC Procedure #5

Metastron typically is administered on an outpatient basis. Since Strontium-89 is a pure beta-emitter, the patient poses a negligible radiation hazard to those near him, therefore patients receiving injections may be released immediately after injection. No bioassay of patients is necessary. Strontium-89 chloride is a calcium analog, and as such will selectively localize in bone mineral, however, bodily fluids such as blood and urine will contain some amount of radioactivity especially during the first few days following injection. Patients are instructed to flush the toilet twice (conventional 5 gallon) and to swab carefully any bleeding cuts. Special precautions are necessary for nursing or pregnant mothers.

Douglas Henderson PhD., R.S.O.

11/05/93

GUIDELINES FOR THE CALIBRATION OF METASTRON® (Strontium-89 Chloride Injection)

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%.

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. 4.60 mCi]). 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. Please note that different dose calibrators may have different Sr-89 settings and that the above procedure should be repeated for each individual dose calibrator used to measure Sr-89. Additionally, it may be found that a potentiometer setting giving the calculated activity directly cannot be found and that even on the maximum potentiometer setting the indicated activity is much lower than expected. This is because the signal produced in the dose calibrator is relatively small and cannot be converted into the normal mCi activity range. Amersham Healthcare, for example, has found that on certain dose calibrators, using a potentiometer setting of around 600, a calibration factor of 100 has to be introduced in order to get the correct activity. In these cases the activity indicated on the dose calibrator read-out has to be multiplied by a factor of 100 in order to give the correct mCi activity, thus for a 4 mCi activity the read-out would indicate 40 uCi.

An identical procedure may be followed with the Metastron in a syringe. 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].) This concentration should then be multiplied by the volume of Metastron drawn into the syringe to give the total activity in the syringe. 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. 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®.

Alternatively, the following method can be used to determine the activity in the syringe: after determining the total activity in the shipping vial draw the required dose into the syringe. 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.

For subsequent vials/syringes of Metastron dial in the appropriate Sr-89 potentiometer setting as previously established by the methods outlined above. Place the vial/syringe in the dose calibrator and measure the activity. Consult the label and the decay chart in the package insert and determine the expected activity in the vial/syringe to confirm agreement.

Table 1: Decay of Strontium-89

Day*	Factor	Day*	Factor
-24	1.39	+6	0.92
-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.)

RADIATION ONCOLOGY WILL CALL THE NUCLEAR MEDICINE DEPARTMENT TO SCHEDULE PATIENTS FOR STRONTIUM INJECTION.
WHEN STRONRIUM ARRIVES IT WILL CHECKED IN PER RADIOACTIVE SHIPMENT PROTOCOL. USE SETTING 574 TO CALIBRATE.

PROCEDURE: A BUTTERFLY NEEDLE WITH A THREE WAY STOPCOCK IS INSERTED INTO A VEIN. USE AT LEAST A 10CC SALINE FLUSH. INJECTION SHOULD BE GIVEN OVER A 5-10 MIN PERIOD. INJECT SMALL AMOUNT OF STRONTIUM AND FLUSH THRU TUBING,REPEAT PROCEDURE UNTIL THE STRONTIUM IS COMPLETELY INJECTED.
DR. ANDERSON MUST BE PRESENT FOR THE INJECTION.
PRIOR TO INJECTION DR. ANDERSON WILL COUNCIL PATIENT ON WHY AND WHAT THE STRONTIUM IS USED FOR. A CONSENT FORM MUST BE SIGNED BY THE PATIENT PRIOR TO THE ADMINISTRATION OF THE STRONTIUM.

IF THE STRONTIUM IS INJECTED TOO FAST YOU MAY NOTICE A REDDENING UP THE PATIENTS ARM. CARE SHOULD BE TAKEN NOT TO INJECT STRONTIUM TOO FAST.

AFTER THE STRONTIUM INJECTION THE USED NEEDLES AND SYRINGES ARE PLACED IN A SEPERATE BIN FOR DECAY STORAGE (555 DAYS).

PATENT WILL BE FOLLOWED UP BY DR. ANDERSON.

EXAM CHARGE: RADTHERAPY RADIONUCLIDE THERAPY 9179400
PROCEDURE CHARGES: META METASTRON 9190230
INTRO VEIN INTRO NEEDLE IN VEIN 9738000