Hospital of
Saint Raphael

1450 Chapel Street
New Haven, Connecticut 06511

December 7, 1994

USNRC
Washington,DC 20555

DOCKET NO. 030-01238
LICENSE NO. 06-00200-03
SUBJECT: REPLY TO NOTICE OF VIOLATION

Dear Sir:

This letter is in reply to a notice of violation resulting from NRC routine inspection No. 030-01238/94-001, conducted by Mr. Ihor Czerwinskyj of the Region I office on October 24 and 25of this year at The Hospital of Saint Raphael in New Haven, CT. We have chosen to respond to the individual violations in the same order as they were presented in, Appendix A, Notice of Violation (attached).

A. Violation: As of October 25, the Quality Management Program (QMP) did not include a written procedure for the use of Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions.

Reply: Revisions to the Quality Management Program were submitted to the Region I Quality Management Program Coordinator in November of 1994. Included among the revisions was a separate Written Directive Worksheet for the use of the Strontium-90 Eye Applicator (see attached). Acknowledgement of the revised QMP was received from the Region I QMP coordinator on November 24, 1994. All uses of the Strontium-90 Eye Applicator from 11/24/94 onward require the utilization of the Written Directive Worksheet, which is in accord with Regulatory Guide 8.33, QualityManagement Program.

B. Violation: On July 8, 1993, a survey for removable contamination was not done before assigning another patient to Room 4594 of the Celentano patient wing. This room was the room of a patient who had received radiopharmaceutical therapy and had been hospitalized for compliance with 10CFR 35.75.

Reply: Established written procedures for hospitalized patients who receive I-131 therapy require that a decontamination survey of the room be performed by the RSO prior to the room being released for other uses. On the date in question, the RSO was on vacation and the radiation safety procedures attendent to the I-131 patient were performed by the authorized user. A survey of the I-131 treatment log and the patient's chart confirmed that there was no record of a decontamination survey. The authorized user is very experienced in the radiation safety procedures required for I-131 patients. One possible reason for the omission of the survey could be that the I-131 treatment log did not contain a specific section for the entry of the results of the decontamination survey. The entries had been made by the RSO by writing a note in the lower right corner of the treatment log. Thus, during the treatment of the patient in question, there was no visual reminder to the authorized user that a survey needed to be done. The I-131 treatment log has been revised (see attached) to include a section which queries the individual responsible for completing the log as to whether the required decontamination survey has

IE07

been done. Time and date of the survey, verification that removable contamination is less than 200 dpm/100 sq cm, and initials of the surveyor are required. Verification of the contamination level will be performed with instrumentation (3" Well Crystal with Multichannel Analyzer) capable of detecting 200 dpm/100sq cm of I-131 contamination. Swipe tests will be done on areas deemed most likely to contain contamination. This revised procedure will go into effect as of 12/7/94.

C. Violation: On November 18, 1993, Cs-137 brachytherapy sources were implanted into a patient who was hospitalized without the performance of a survey of the dose rates in restricted and unrestricted areas contiguous to the room of the implanted patient.

Reply: Established procedures call for a survey of restricted and unrestricted areas following implantation of Cs-137 sealed sources. The logsheet for these procedures contained a section for logging the dose rates at selected points in and around the room. The authorized user who implanted the sources could not verify whether or not a survey was performed. Since procedures detailing the need to perform a survey already exist, it will be necessary for a second individual (either a medical dosimetrist or a radiation physicist) to accompany the authorized user to the patient's room to perform the survey. A separate radiation survey form has been devised (see attached) to contain a scaled drawing of the room utilized for brachytherapy implants. The form has specific locations where exposure rate measurements must be taken and recorded. Upon return to the Radiation Therapy Department, the individual responsible for the survey will submit the survey logsheet to the RSO for review. The RSO will initial the survey logsheet and record the date and time of review. This procedure will insure that a survey will be performed on every brachytherapy implant patient. This procedure is in place as of 12/7/94.

Sincerely,

Michael T. Koff

Michael T. Koff
Director, Ancillary Services

c : Regional Administrator,
Region I
USNRC

Brachytherapy Quality Management Program
Written Directive Worksheet
For Use of Strontium-90 Eye Applicator

Written Directive:

Planned Date of Application:_____
Name of Patient:_____
Treatment Site:_____
Radioisotope:_____
Source Activity (mCi):_____
Source Output (rads/sec):_____
Treatment Time (seconds):_____
Treatment Dose (rads):_____
Authorized User Signature:_____
Date:_____

==========

Warning To Individuals Carrying Out Written Directive:

If any confusion exists as to how to carry out the written directive, you are required to consult with the authorized user who completed the written directive prior to continuing the procedure.

==========

Verification of Patient Identification:

Verification of patient ID accomplished by asking the patient his/her name and one of the following: (circle one)

birth date address ss# checked ID bracelet

==========

Verification of Administration/ Agreement With Written Directive

Date of Administration:_____
Time of Administration:_____
Treatment Site:_____
Radioisotope used:_____
Source Activity (mCi):_____ _____
Source output (rads/sec):_____
Treatment Time (seconds):_____
Treatment Dose (rads):_____
Was administration in accordance with the written directive?_____
Authorized user signature:_____
Date/Time:_____

CEG 10/94

I-131 Therapy Record

Patient Name:_____ Physician Name:_____

Date of Administration:_____ Patient Room #:_____

Manufacturer's Lot Number(s):_____

Manufacturer's Assay:_____ Date/Time of Assay:_____

HSR Assay:_____ Date/Time of Assay:_____

Date/Time of Administration of Isotope: _____

Written Directive checked prior to administration to patient?:___

Residual vial assay results:_____

Activity administered to patient:_____

Initials of individual administering isotope:_____

Date/Time of Radiation Exposure Survey:_____ _____

Survey form placed ino patient's therapy chart?:_____

Initials of individual performing survey:_____

Measurement of Residual Activity Within Patient:

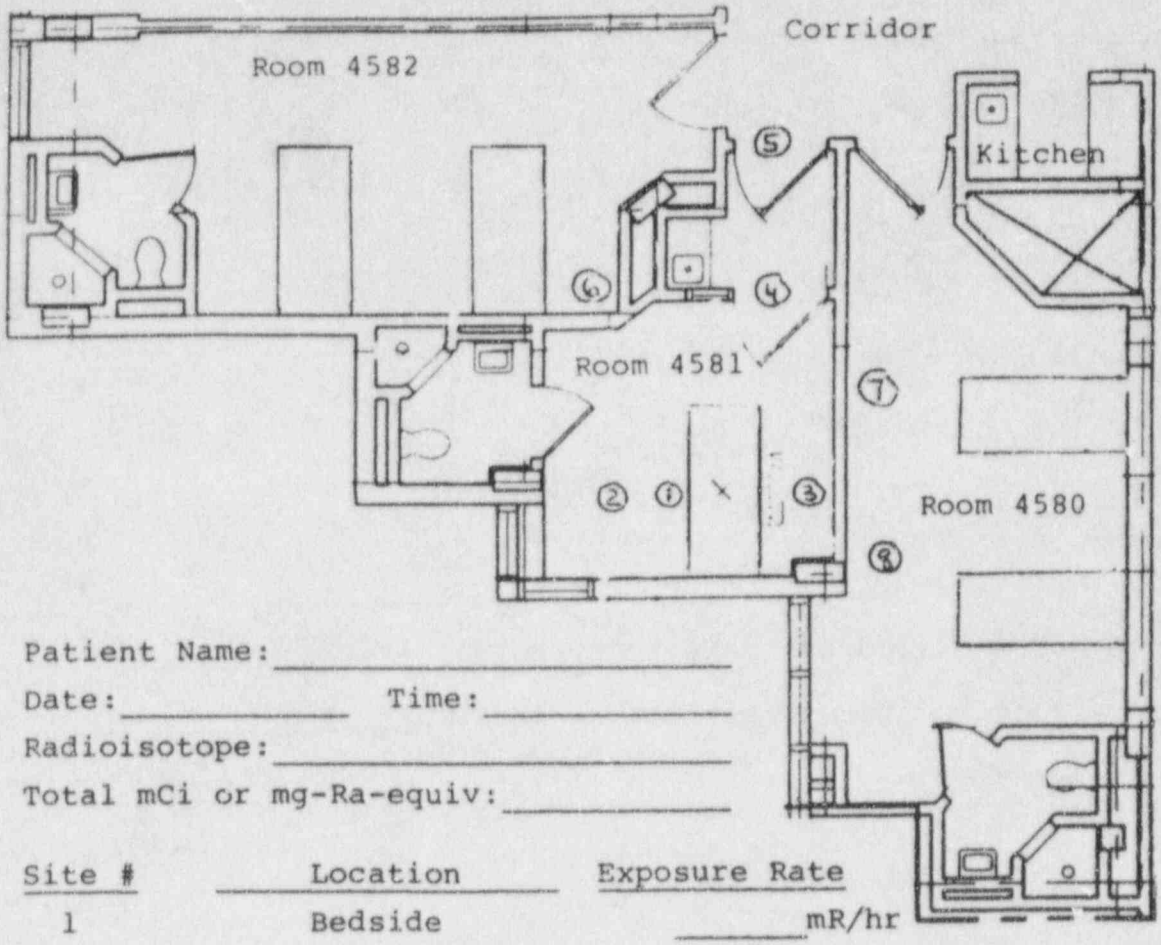
Date:	_____	_____	_____	_____	_____
Time:	_____	_____	_____	_____	_____
mr/hr @ 1 meter:	_____	_____	_____	_____	_____
Residual actvity	_____	_____	_____	_____	_____
Initials:	_____	_____	_____	_____	_____

Date/Time of discharge of Patient:_____
Exposure rate at 1 meter from patient at discharge:_____
Estimated residual activity in patient at discharge:_____
Initials of individual making measurements:_____

Decontamination Survey of Patient Room:

Time/Date of survey:_____ (Attach survey results)
Does survey show removeable contamination <200dpm/100sq cm?:_____
Has all contaminated waste been placed in storage for decay?:____
Initials of individual releasing room for general use:_____

Hospital of Saint Raphael
Area Radiation Survey Diagram
Celentano Room 4581



Patient Name: _____

Date: _____ Time: _____

Radioisotope: _____

Total mCi or mg-Ra-equiv: _____

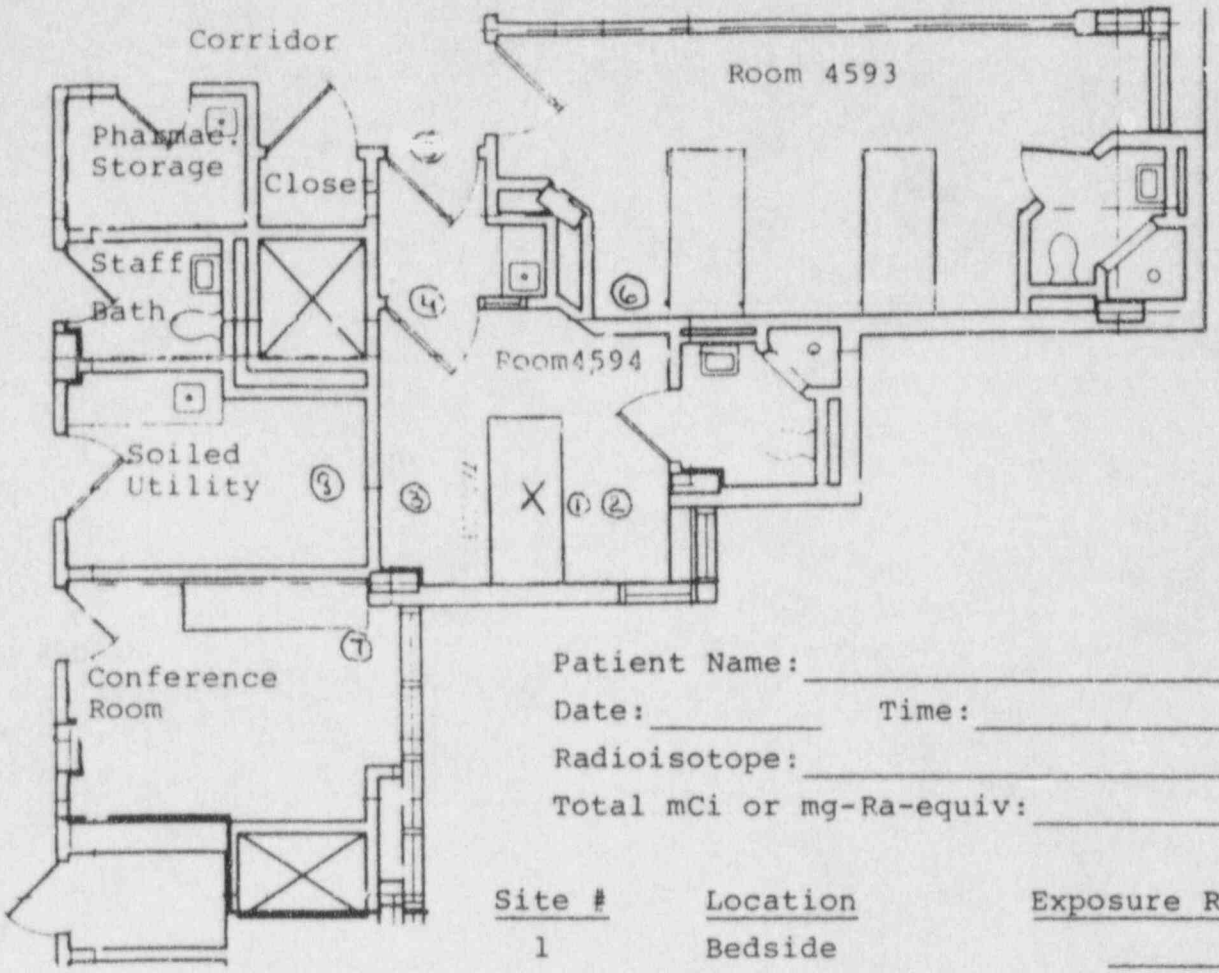
Site #	Location	Exposure Rate
1	Bedside	_____ mR/hr
2	3 ft Away	_____
3	3 ft Away	_____
4	Inner Doorway	_____
5	Outer Doorway	_____
6	Room 4582	_____
7	Room 4580	_____
8	Room 4580	_____

Survey Meter Used
Manufacturer: _____
Model No. : _____
Serial No. : _____

Survey Performed By: _____
(signature)

CEG 10/94

Hospital of Saint Raphael
Area Radiation Survey Diagram
Celentano Room 4594



Patient Name: _____

Date: _____ Time: _____

Radioisotope: _____

Total mCi or mg-Ra-equiv: _____

Site #	Location	Exposure Rate, mR/hr
1	Bedside	_____
2	3 ft Away	_____
3	3 ft Away	_____
4	Inner Doorway	_____
5	Outer Doorway	_____
6	Room 4593	_____
7	Conference Rm	_____
8	Soiled Utility	_____

Survey Meter Used

Manufacturer: _____

Model No. : _____

Serial No. : _____

Survey Performed By: _____
(signature)

CEG 10/94