

**ATTACHMENT 2**

10 CFR 35.75 SEVERITY LEVEL IV VIOLATIONS FOR I-131 THERAPY

**SAFETY AND COMPLIANCE INSPECTION**

<p>1. LICENSEE                  SOUTH JERSEY HOSPITAL                  MILLVILLE, BRIDGETON AND NEWCOMB                  1000 NORTH HIGH STREET                  MILLVILLE, NJ 08332                  REPORT NUMBER(S) 0001-001</p>	<p>2. REGIONAL OFFICE                  REGION I                  US NUCLEAR REGULATORY COMMISSION                  475 ALLENDALE ROAD                  KING OF PRUSSIA PA 19406-1415</p>
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<p>3. DOCKET NUMBER(S)                  036 02578</p>	<p>4. LICENSE NUMBER(S)                  29-18911-01</p>	<p>5. DATE(S) OF INSPECTION                  8-16+17-2001</p>
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**LICENSEE:**  
 The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied. \_\_\_\_\_ non-cited violation(s) were discussed involving the following requirement(s): \_\_\_\_\_
- 3. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which is required to be posted in accordance with 10 CFR 19.11.

10 CFR 35.75 REQUIRES THAT THE LICENSEE SHALL MAINTAIN A RECORD FOR 3 YEARS THAT INSTRUCTIONS WERE PROVIDED AND THE BASIS FOR RELEASING THE INDIVIDUAL

CONTRARY TO THE ABOVE YOU DID NOT MAINTAIN A RECORD OF THE BASIS FOR RELEASE OF AN INDIVIDUAL

THE LICENSEE STATED THEY WILL REVIEW ALL ADMINISTRATIONS IN ACCORDANCE WITH THE INSTRUCTIONS IN 10CFR GUIDE 2.39 AND WILL INSERT ALL INDIVIDUALS INVOLVED IN ADMINISTRATION

**STATEMENT OF CORRECTIVE ACTIONS**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	WAYNE SCHIFFMIR		8-17-01
NRC INSPECTOR	DAVID S EVERHART		8-17-01

**APPENDIX A  
NUCLEAR MEDICINE INSPECTION RECORD (IP 87115)**

REGION I

Report # 2001-001 License # 29-13911-01 Docket # 030-02578

Licensee Name South Jersey Hospital System, Millville, Bridgeton and Newcomb

Street Address 1200 North High Street

City, State, Zip Millville, New Jersey 08332

Location (Authorized Site) Being Inspected  
Bridgeton and Newcomb

Licensee Contact Name Paul Chase, DO, RSO. Phone # 856 825-3500

Priority 3 Program Code 2120 Description

Last Inspection: Sept. 27 & 28, 2000 This Inspection Aug. 16 & 17, 2001

Type of Insp. Announced Unannounced **XX**

Routine **XX** Special Initial

Next Insp. Date 8/2004 Normal **X** Reduced Extended

Justification for change in normal inspection frequency:

**Summary of Findings and Actions**

No violations, Clear 591 or letter issued Non-cited violations

Violation(s), 591 issued **X** Violation(s), letter issued

Follow up on previous violations: **None**

Inspector -Signature

*/RA/*

10/13/01

- Printed Name

**David B. Everhart**

Date

Approved - Signature

*/RA/*

10/10/01

- Printed Name

**William H. Ruland**

Date



## PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

### 1. AMENDMENTS AND PROGRAM CHANGES

License amendments issued since last inspection, or program changes noted in the license.

AMENDMENT #	DATE	SUBJECT
46	4/30/01	Relocate Nuclear Medicine
45	1/17/01	Add use and storage of Brachytherapy sources at Newcomb
44	10/4/2000	Add the use of Xenon133 at Bridgeton facility

### 2. INSPECTION AND ENFORCEMENT HISTORY

Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.

None

### 3. INCIDENT/EVENT HISTORY

List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

None

## PART II (NUCLEAR MEDICINE- 87115) - INSPECTION DOCUMENTATION

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87115, Appendix B, "Nuclear Medicine Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable. All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

### 1. ORGANIZATION AND SCOPE OF PROGRAM

Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects.

**This inspection was conducted to review the effect of the addition of Newcomb Hospital as a place of use on their license and to make all the facilities inspection dates current. The license currently has a total of three locations of use, an increase from two locations of use since the last inspection. The last inspection of the Newcomb license was in 1998. The last inspection of the rest of the facilities on the license was in September, 2000. The inspection also evaluated any change in oversight due to the additional facility and a review of the move of the brachytherapy program to the Newcomb facility. The inspection included a limited review of the Nuclear Medicine program at the Bridgeton location of use.**

**The RSO reports directly to management for all radiation safety needs. Management is very responsive to the RSO for radiation safety needs. The RSO has appropriate authority and responsibility to fulfill the required responsibilities. The license lists three locations of use and these were noted during the inspection. The licensee performs routine nuclear medicine procedures including bone and cardiac studies and lung scans using Xenon and thyroid uptakes and scans and therapy for hyperthyroidism. The Newcomb facility has three full-time technologists with three cameras. The licensee does not provide mobile nuclear medicine services, limited distribution of radiopharmaceuticals nor do they perform research involving human subjects.**

### 2. MANAGEMENT OVERSIGHT

Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; and program audits, including as low as is reasonably achievable (ALARA) reviews.

**Management is supportive of radiation safety. The RSO has good support from medical physics and administrative technologists in nuclear medicine. The inspector reviewed the RSC meetings since the last inspection and found proper representation**

and good discussions of pertinent issues. The RSC also reviewed the ALARA review of the monthly dosimetry reports. Program audits were performed by a consultant health physicist and reviewed by the RSC.

### 3. FACILITIES

Facilities as described; uses; control of access; and engineering controls.

**The facilities and uses were as described. Control of access to the hot lab at both the Bridgeton facility is accomplished by direct supervision and keypad locked doors. Control of access at the Newcomb facility is accomplished through keyed locks and direct oversight. Management discussed the feasibility of adding keypad locks to the Newcomb facility. Surveys of xenon trap effluent and room negative pressure tests were performed monthly.**

### 4. EQUIPMENT AND INSTRUMENTATION

Dose calibrator; instrumentation for assaying alpha- emitting and beta-emitting radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.

**The licensee possesses and uses an Capintec CRC-7 which has had linearity and accuracy performed as required from 1998 to the present. The licensee has not moved the dose calibrator and has not performed a geometry evaluation since the last inspection. The licensee does not use a generator but syringe and vial shields were noted and observed in use during the inspection. The inspector noted one operable and properly calibrated survey instrument. Records indicate the licensee obtains a replacement survey meter from the radiopharmacy when they send their survey instrument in for calibration. No Part 21 procedures implemented or required.**

### 5. MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material.

**Materials noted in use through direct observation and records reviews were authorized. Control over licensed material was noted to be adequate throughout the inspection at all facilities. Interviews with individuals revealed an adequate understanding of requirements and good radiation safety practices, commensurate with their level of use.**

### 6. RADIOPHARMACEUTICAL THERAPY

Safety precautions; surveys; and release criteria of patients and rooms.

**No patients were hospitalized in compliance with 10 CFR 35.75. Three patients were given doses greater than 33 mCi of I<sup>131</sup> and released with instructions in July of 2001. Patients were counseled and this was well documented. The authorized user was not aware of the need for performing a calculation to assure compliance with 35.75. Subsequent calculations revealed that the release of these patients met the release criteria in Regulatory Guide 8.39 which is used to show compliance with 10 CFR 35.75.**

These administration had not been reviewed with the consultant physicist. The authorized user is now fully aware of the requirement and will train all other individuals of this requirement. All technologists involved in thyroid treatments will also be in-serviced in the requirement. This was an isolated incident and was not indicative of a breakdown in the overall radiation safety program. The corrective actions proposed were acceptable and the inspector cited the violation on the NRC Form 591.

## **7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS**

QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records.

The licensee performed a QMP audit in January of 2001. Individuals interviewed exhibited an adequate understanding of procedures, requirements and good safety practices. A review of 48 (100% of the administrations in 98 to 01) I<sup>131</sup> therapy administrations in the Newcomb facility revealed no misadministrations and no recordable or reportable events. A review of 12 of the 29 administrations at the Bridgeton facility revealed no misadministrations and no recordable or reportable events.

## **8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL**

Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses.

Surveys were reviewed for both the Newcomb and the Bridgeton facilities. Surveys were performed as required and the results were documented, including minor spills with appropriate follow-up. Leak tests and inventories were performed and recorded as required. Observations and interviews with individuals revealed an adequate understanding and implementation of radiation safety requirements when handling radioactive materials. Public dose was not inspected.

## **9. TRAINING AND INSTRUCTIONS TO WORKERS**

Interviews and observations of routine work; staff knowledge of all routine activities; requirements; therapy training and postulated emergency situations; supervision by authorized users. 10 CFR Part 20

Interviews and observations revealed an adequate understanding of requirements and good safety practices commensurate with their level of use. Individuals revealed an adequate understanding of Part 20 requirements and normal and postulated emergency situations. Supervision of individuals by authorized users was adequate.

## **10. RADIATION PROTECTION**

Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release.

The licensee supplies monthly dosimetry. The RSO performs an ALARA review at each RSC meeting . A review of the dosimetry records from 1/98 to 6/01 revealed a maximum reading of:1680 mRem per year, extremity dose; and 280 mRem whole body TEDE dose per year. See Item 6 regarding patient release.

**11. RADIOACTIVE WASTE MANAGEMENT**

Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records.

**The licensee disposes of radioactive materials using decay-in-storage and disposal as hazardous waste.**

**12. DECOMMISSIONING**

Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements.

**Not inspected.**

**13. TRANSPORTATION**

Quantities and types of licensed material shipped; packaging design requirements; hazardous materials (HAZMAT) communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

**The licensee receives unit doses and returns used and unused doses to the radiopharmacy. Interviewed individuals exhibited an adequate understanding of proper receipt requirements and procedures as well as proper transfer procedures including limited quantity limits. HAZMAT training not inspected.**

**14. NOTIFICATIONS AND REPORTS**

Theft; loss; incidents; overexposures; change in Radiation Safety Officer (RSO), authorized user, or nuclear pharmacist; and radiation exposure reports to individuals.

**No theft, loss, incidents, overexposures or changes in RSO or authorized user.**

**15. POSTING AND LABELING**

Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material.

**Posting of radiation areas and labeling of containers was noted as required. Notices bulletins and generic information was received, reviewed and filed appropriately. Licensee documents were available as required.**

**16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS**

Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date.

Surveys were performed with a Ludlum 14C with an end window probe. NRC number 033504, last calibrated January, 2001. Surveys of the brachytherapy patient room revealed 0.2 mR/hr at the door, 0.7 mR/Hr in the adjacent room and 0.4 mR/hr in the stairway. Background was measured at 0.04 mR/hr. Surveys of the outside adjacent areas of the brachytherapy room were equal to background. Surveys were also performed at Newcomb facility. Background was noted at 0.03 mR/hr. Readings of the hot lab, camera rooms stress rooms and adjacent areas revealed reading equal to background. Readings were compatible with readings noted on area surveys.

**17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs) AND OTHER SAFETY ISSUES**

State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

The licensee performed three I<sup>131</sup>thyroid therapy administrations in July of 2001, with greater than 33 mCi, the limit in Reg Guide 8.39, and failed to perform calculations to ensure that the dose to the individual likely to receive the highest dose was less than 500 mRem in accordance with 10 CFR 35.75. The licensee initially was not aware of the requirement to perform the calculation and the consultant physicist had not visited the site since the therapies and when the inspection occurred. The consultant physicist was aware of the requirement and subsequently performed the calculation which showed that the dose to the individual would be less than 500 mRem. The RSO is now aware of the requirement and will train all authorized users who might perform therapies and also train the technologists who might participate in the therapy to ensure this does not occur in the future. The inspector cited the violation on Form 591 since this was not a programmatic breakdown and corrective action proposed was adequate to resolve the violation and prevent recurrence. 10 CFR 35.75 requires that the licensee shall maintain a record for three years that instructions were provided and the basis for releasing the individuals. Contrary to the above the licensee did not maintain a record of the basis of the release of the individual.

**18. PERSONNEL CONTACTED**

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).

Use # to indicate individual present at entrance meeting.

Use \* to indicate individual present at exit meeting.

	Name	Title	Phone No.	In Person or By phone
*	Wayne Schiffner	Chief Operating Officer		Person
*	Paul V. Chase, DO	Radiation Safety Officer		Person

*	<b>Maria Phillips</b>	<b>Admin Dir Radiology</b>		<b>Person</b>
*	<b>Mario Sergi</b>	<b>Dir, Rad Oncology</b>		<b>Person</b>
*	<b>Marcia Ostroff</b>	<b>Lead Nuc Med Tech</b>		<b>Person</b>
	<b>Sandy Gabriel</b>	<b>Physicist</b>		<b>Person</b>
	<b>Lester</b>	<b>Physicist</b>		<b>Person</b>
	<b>Chris Redington</b>	<b>Nuc Med Tech N</b>		<b>Person</b>
	<b>Teresa Pimpinella</b>	<b>Nuc Med Tech N</b>		<b>Person</b>
	<b>Luz Melendez</b>	<b>Nuc Med Tech N</b>		<b>Person</b>
	<b>Kathy Sinisacki</b>	<b>Contractor Tech N</b>		<b>Person</b>
	<b>Suzanne Ramsey</b>	<b>Contractor Tech B</b>		<b>Person</b>
	<b>Deepak Parikh</b>	<b>Nuc Med Tech B</b>		<b>Person</b>

**19. PERFORMANCE EVALUATION FACTORS**

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.		Y	<input type="checkbox"/>	N	<input checked="" type="checkbox"/>
B.	RSO too busy with other assignments.		Y	<input type="checkbox"/>	N	<input checked="" type="checkbox"/>
C.	Insufficient staffing.		Y	<input type="checkbox"/>	N	<input checked="" type="checkbox"/>
D.	RSC fails to meet or functions inadequately.	N/A	<input type="checkbox"/>	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E.	Inadequate consulting services or inadequate audits conducted.	N/A	<input type="checkbox"/>	Y	<input type="checkbox"/>	<input checked="" type="checkbox"/>

**REMARKS:** (Consider the above assessment and/or other pertinent Performance Evaluation Factors (PEFs) with regard to the licensee's oversight of the radiation safety program.)

<b>PART III - POST- INSPECTION ACTIVITIES</b>	
<b>1.</b>	<b>REGIONAL FOLLOWUP ON PEFs</b>
<b>None</b>	

<b>2.</b>	<b>DEBRIEF WITH REGIONAL STAFF</b>
Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.	

**Reviewed with Branch Chief**

## **PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY**

### **1. AMENDMENTS AND PROGRAM CHANGES**

License amendments issued since last inspection, or program changes noted in the license.

AMENDMENT #	DATE	SUBJECT
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**See Nuc Med Inspection Record**

### **2. INSPECTION AND ENFORCEMENT HISTORY**

Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.

**See Nuc Med Inspection Record**

### **3. INCIDENT/EVENT HISTORY**

List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

**See Nuc Med Inspection Record**

## **PART II (BRACHYTHERAPY - 87118) - INSPECTION DOCUMENTATION**

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87118, Appendix B, "Brachytherapy Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

### **1. ORGANIZATION AND SCOPE OF PROGRAM**

Management organizational structure; Radiation Safety Officer (RSO) and chairman of Radiation Safety Committee (RSC); authorized locations of use; type, quantity, and frequency of byproduct material use.

**The main purpose of this inspection was to review the administrative oversight changes since the actual change of control occurred which included the Newcomb facility on the license and including the move of the brachytherapy program to the Newcomb facility. See the Nuclear Medicine Inspection Record for more information.**

**2. MANAGEMENT OVERSIGHT**

Management support to radiation safety; RSC; RSO; program audits or inspections; as low as reasonably achievable (ALARA) reviews; control and supervision by authorized users.

**See Nuclear Medicine Inspection Record**

**3. FACILITIES**

Facilities as described; uses; control of access; engineering controls; shielding; maintenance by authorized persons; remote afterloader facilities; pulsed-dose-rate afterloader facilities; low-dose-rate afterloader facilities; interlocks; patient monitoring; approved locations of use.

**The inspector reviewed the new storage location for brachytherapy sources including surveys performed in the storage room and surrounding locations. The licensee was also performing a brachytherapy procedure the inspection and the inspector performed surveys and compared the results with the surveys performed by the licensee.**

**4. EQUIPMENT AND INSTRUMENTATION**

Operable and calibrated survey instruments and dosimetry; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors; backup power supplies for monitors and afterloaders; equipment inspected as scheduled; emergency equipment; calibration and maintenance by authorized persons.

**See Nuclear Medicine Inspection Record**

**5. MATERIAL USE, CONTROL, AND TRANSFER**

Materials and uses authorized; afterloader sources approved; security and control of licensed materials; procedures for receipt and transfer of licensed material; source installation and replacement by authorized persons; patient surveys and release.

**See Nuclear Medicine Inspection Record**

**6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL**

Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; records and reports; public doses; unrestricted area surveys; use of protective clothing; proper waste disposal; shielding.

**See Nuclear Medicine Inspection Record**

**7. TRAINING AND INSTRUCTIONS TO WORKERS**

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Training and retraining requirements for authorized users and operators; documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response and training for operators, physicians, nurses, and medical physicists; use and supervision by authorized users.

**See Nuclear Medicine Inspection Record**

**8. OPERATING AND EMERGENCY PROCEDURES FOR REMOTE AFTERLOADERS**

Operating and emergency procedures posted; procedures approved; required persons present during afterloader use; surveys in unrestricted areas; leak testing; inventories.

**Not applicable**

**9. RADIATION PROTECTION**

Radiation protection program with ALARA provisions; access control; dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications.

**See Nuclear Medicine Inspection Record**

**10. QUALITY MANAGEMENT (QM) PROGRAM, MISADMINISTRATIONS, AND REPORTABLE EVENTS**

Verify QM program administration and records and reports of misadministrations and events.

**See Nuclear Medicine Inspection Record**

**11. RADIOACTIVE WASTE MANAGEMENT**

Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal methods.

**See Nuclear Medicine Inspection Record**

**12. DECOMMISSIONING**

Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.

**See Nuclear Medicine Inspection Record**

**13. TRANSPORTATION**

Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials HAZMAT communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

**See Nuclear Medicine Inspection Record**

**14. NOTIFICATIONS AND REPORTS**

Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals.

**See Nuclear Medicine Inspection Record**

**15. POSTING AND LABELING**

Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material.

**See Nuclear Medicine Inspection Record**

**16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS**

Areas, both restricted and unrestricted, surveyed, and comparison of data with licensee's results and regulations; and instrument type and calibration date.

**See Nuclear Medicine Inspection Record**

**17. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES**

State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

**See Nuclear Medicine Inspection Record**

**18. PERSONNEL CONTACTED**

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).

Use # to indicate individual present at entrance meeting.

Use \* to indicate individual present at exit meeting.

Name	Title	Phone No.	In Person or By phone
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**See Nuclear Medicine Inspection Record**

**18. PERFORMANCE EVALUATION FACTORS (PEFs)**

A. Lack of senior management involvement with the radiation safety program and/or RSO oversight		Y	<input type="checkbox"/>	N	<input type="checkbox"/>
B. RSO too busy with other assignments		Y	<input type="checkbox"/>	N	<input type="checkbox"/>
C. Insufficient staffing		Y	<input type="checkbox"/>	N	<input type="checkbox"/>
D. Radiation Safety Committee fails to meet or functions inadequately	N/A	<input type="checkbox"/>	Y	<input type="checkbox"/>	N
E. Inadequate consulting services or inadequate audits conducted	N/A	<input type="checkbox"/>	Y	<input type="checkbox"/>	N

**REMARKS:** (Consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program.)

**PART III - POST- INSPECTION ACTIVITIES**

**1. REGIONAL FOLLOWUP ON PEFs**

**None**

**2. DEBRIEF WITH REGIONAL STAFF**

Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.

**See Nuclear Medicine Inspection Record**



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 2, 2005

Docket No. 03014474

License No. 37-18104-01

Darlette Tice  
Vice President of Operations & Chief Nursing Officer  
Forbes Regional Hospital  
2570 Haymaker Road  
Monroeville, PA 15146-3592

SUBJECT: INSPECTION 03014474/2005001, FORBES REGIONAL HOSPITAL,  
MONROEVILLE, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Ms. Tice:

On January 24 and 25, 2005, Richard McKinley of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you and others of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

D. Tice  
Forbes Regional Hospital

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Your cooperation with us is appreciated.

Sincerely,

***Original signed by Pamela J. Henderson***

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

Enclosure:  
Notice of Violation

cc:  
Stephen R. DeLong, M.D., Radiation Safety Officer  
Commonwealth of Pennsylvania

D. Tice  
Forbes Regional Hospital

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## NOTICE OF VIOLATION

Forbes Regional Hospital  
Monroeville, PA

Docket No. 03014474  
License No. 37-18104-01

During an NRC inspection conducted on January 24 and 25, 2005, one violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

- A. 10 CFR 35.75(a) states that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, the licensee failed to ensure that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Specifically, on July 23, 2004, and September 3, 2004, the licensee administered 149.5 mCi and 159.4 mCi, respectively, of iodine-131 to patients and released them from its control without doing the calculations necessary to ensure that the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 mSv (0.5 rem).

This is a Severity Level IV violation (Supplement VI ).

Pursuant to the provisions of 10 CFR 2.201, Forbes Regional Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at <http://www.nrc.gov/reading-rm.html>. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made

publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 2 day of February 2005



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 14, 2008

Docket No. 03035600

License No. 29-30606-01

Jill Baer  
Administrator  
Central Jersey Radiologist  
2128 Kings Hwy. & Route 35  
Oakhurst, NJ 07755

SUBJECT: INSPECTION 03035600/2008001, CENTRAL JERSEY RADIOLOGIST,  
OAKHURST, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Ms. Baer:

On September 16, 2008, Michelle Simmons of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Jill Baer, John Phander of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC; How We Regulate; Enforcement**; then **Enforcement Policy**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

J. Baer

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Please contact Michelle Simmons at 610-337-6921 if you have any questions regarding this matter.

Sincerely,

***Original signed by Sandra Gabriel for***

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

Enclosure  
Notice of Violation

cc:  
Irving Stein, D.O., Radiation Safety Officer  
State of New Jersey

J. Baer

2

Please contact Michelle Simmons at 610-337-6921 if you have any questions regarding this matter.

Sincerely,

**Original signed by Sandra Gabriel for**

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

Enclosure  
Notice of Violation

cc:  
Irving Stein, D.O., Radiation Safety Officer  
State of New Jersey

Distribution:  
D. J. Holody, RI

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**SUNSI Review Complete: MSimmons**

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DATE	10/16/08		10/20/08				

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## **NOTICE OF VIOLATION**

Central Jersey Radiologist  
Oakhurst, NJ

Docket No. 03035600  
License No. 29-30606-01

During an NRC inspection conducted on September 16, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1501(a)(2) states in part, that each licensee shall make or cause to be made, surveys that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and the potential radiological hazards.

10 CFR 35.75(a) states that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, the licensee did not make or cause to be made, surveys that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels. Specifically, on November 28, 2007, June 12, 2008, and July 1, 2008, the licensee did not perform surveys in accordance with 10 CFR 35.75(a), on a patient after being administered sodium iodide iodine -131 in quantities exceeding 33 millicuries to determine if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

This is a Severity Level IV violation (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Central Jersey Radiologist is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 14 day of October 2008