



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

March 20, 2001

Docket No. 03002481

License No. 29-05084-02

Neil Hudes  
Vice President, Professional Services  
Hunterdon Medical Center  
Route 31  
Flemington, NJ 08822-4604

SUBJECT: INSPECTION 03002481/2001001, HUNTERDON MEDICAL CENTER,  
FLEMINGTON, NEW JERSEY SITE

Dear Mr. Hudes:

On February 20, 2001, Penny Lanzisera 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. Additional information provided in your correspondence dated February 23, 2001 was also examined as part of the inspection. The findings of the inspection were discussed with you and Mr. Ryan of your organization at the conclusion of the inspection.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

***Original signed by Mohamed M. Shanbaky***

Mohamed M. Shanbaky, Chief  
Nuclear Materials Safety Branch 1  
Division of Nuclear Materials Safety

cc:

Alice Q. Sprenger, M.D., Radiation Safety Officer  
State of New Jersey

DOCUMENT NAME: C:\29-05084-02.2001001.032120~.wpd

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	PLanzisera/pl		MShanbaky/ms			
DATE	3/6/01		3/20/01			

OFFICIAL RECORD COPY

APPENDIX A

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Region I

Inspection record No. 2001-001

License No. 29-05084-02

Licensee (Name and Address):

Docket No. 030-02481

Hunterdon Medical Center  
Route 31  
Flemington, NJ 08822-4604

Location (Authorized Site) Being Inspected:

same as above

Licensee Contact: Dr. Alice Sprenger

Telephone No. 908-788-6100

Priority: 3

Program Code: 2120

Date of Last Inspection: 3/19/98

NMED/Event No(s): none

Date of This Inspection: 2-20-01 & review of additional information received 2-27-01

Type of Inspection:

( ) Announced

(X) Unannounced

(x) Routine

( ) Special

( ) Initial

Next Inspection Date 2/05 ( ) Normal ( ) Reduced (x) Extended

Justification for change in normal inspection frequency:

**clear inspections 98-001 and 2001-001**

Summary of Findings and Actions:

(X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued

( ) Non-cited violations

( ) Violation(s), Form 591 issued

( ) Violation(s), regional letter issued

( ) Followup on previous violations

Inspector(s) /RA/

Date 3-6-2001

(Sign Name)

Penny Lanzisera

(Print Name)

Approved /RA/

Date 3/20/2001

(Sign Name)

Mohamed Shanbaky

(Print Name)

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

1. INSPECTION AND ENFORCEMENT HISTORY:  
(Unresolved issues; previous and repeat violations including NCVs; Confirmatory Action Letters; and orders)

**Clear inspections in 98-001 and 95-001**

2. INCIDENT/EVENT HISTORY:  
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that the NRC nuclear material events database, regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

**None**

## PART II - INSPECTION DOCUMENTATION

*The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all focus elements are to be addressed during each inspection.*

*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)

**2 full-time and 2 part-time nuclear medicine technologists→ Director, Medical Imaging (Leo T. Ryan) → VP, Professional Services (Neil Hudes).**

**Location of use as described in the license. 13-15 patients/day (75% hearts and rest are bone scans, lung studies with xenon, and thyroid). 1-2 hyperthyroid treatments/week with 10-15 millicuries of I-131. No thyroid carcinoma treatments, no 35.500 uses (use x-ray instead) and no radioimmunoassay.**

2. PERSONNEL CONTACTED:

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

**\*Barbara Cooper, NMT**  
**Amy Anderson, NMT**  
**\*Leo Ryan, Director**  
**\*Neil Hudes, VP**  
**John Ramsey, physicist**

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:  
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

**Hot Lab: 0.5 mR/hour in the general area and 2 mR/hour next to source storage**  
**Scan Rooms: background (0.02mR/hr). All readings comparable to licensees and taken with a Ludlum 14c (w/pancake probe), calibrated 4/6/00.**

4. OTHER:  
(e.g., posting and labeling)

**Posting and labeling as required.**

### **PART III - FOCUS ELEMENTS**

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS  
YES **x** NO \_\_\_

(Adequate program reviews, including corrective actions for licensee findings and NRC-identified violations; resources [financial and personnel] dedicated to the program; recurring problems; radiation safety officer [RSO] present; RSO authority and effectiveness; radiation safety committee involvement [if required]; management support of program; radioactive material surveys)

**Physics staff conducts instrument calibrations (linearity, chi-square, etc.) and reviews records maintained by nuclear medicine for surveys, dose calibrator constancy, etc. Any deficiencies noted are discussed in the Radiation Safety Committee meetings and immediately corrected.**

2. KNOWLEDGEABLE STAFF AND MANAGEMENT YES **x** NO \_\_\_

(Use by qualified and knowledgeable individuals; safe work practices; all levels of management possess sufficient knowledge to provide effective oversight of the program)

**All interviewed personnel appeared knowledgeable of appropriate radiation safety precautions and regulatory requirements.**

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS

YES  NO

(Offsite contamination events; effective event response; trending as low as reasonably achievable; release pursuant to 10 CFR 35.75; substantial potential for overexposure; monitoring and dose assessment program; release for unrestricted use; notification)

**No off-site contamination events.**

**2000 exposures from badge results: 565 millirem whole body and 1490 millirem extremity.**

4. ADEQUATE SECURITY AND CONTROL OF LICENSED MATERIAL

YES  NO

(Security and control measures commensurate with the hazard of the material involved; inventory; proper ordering, receipt and transfer of RAM; RAM in unrestricted/uncontrolled area; proper shipping; loss of RAM; proper disposal; notification)

**All areas of storage or use of licensed material were observed locked or attended. Radiopharmacy courier is escorted to the hot lab by security who unlocks the hot lab for package delivery. Licensee sends back unused (decayed) and empty syringes to the radiopharmacy.**

5 USE OF LICENSED MATERIAL ONLY AS AUTHORIZED YES  NO

(Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users)

**Authorized users, uses, and locations of use as described in the license. The most recent air flow checks and spilled gas clearance calculations (for xenon-133) could not be located during the inspection. The licensee submitted these in a letter dated 2-23-01 (received 2-27-01). Review of this information confirmed that negative pressure exists in areas used for xenon storage and administration.**

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES YES  NO

(Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records)

**Patient is identified as correct patient by 2 pictures if possible. If only one picture ID is possessed by the patient (e.g., license) then the social security number is verified. Written directives include the dose, the route of administration, the radioisotope, and the authorized users signature and date signed. Revisions to written directives are signed by the authorized user and dated.**

Reviews of written directives and the program are conducted by the physicist and reported to the radiation safety committee. No misadministrations or recordable events were identified by the physicist during the last review. A sampling of written directives were reviewed by the inspector and no misadministrations or recordable events were identified.

#### **PART IV - POST- INSPECTION ACTIVITIES**

1. DEBRIEF WITH REGIONAL STAFF:  
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer, and/or State Liaison Officer)

**Discussed results with branch chief.**

2. OTHER:

**none**

**END**



Hunterdon  
Medical Center

RECEIVED  
REGION 1

2001 FEB 27 AM 11: 46

*Leo T. Ryan, BS, RT, Director  
Department of Medical Imaging Services*

February 23, 2001

Ms. Penny Lanzisera, Health Physicist  
U.S. Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406

Dear Ms. Lanzisera,

I have enclosed a memorandum from my health physicist, John Ramsey, addressing the documentation that we could not locate during your inspection of 2/21/01.

If you have any further questions, please call me at 908-788-6374.

Sincerely,

Leo T. Ryan, BS, RT, CNMT  
Director

Cc: Neil Hudes, VP, Professional Services

2100 Wescott Drive, Flemington, New Jersey 08822 908-788-6374

**H . M . C .**  
M E M O R A N D U M

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**to:** Leo Ryan, Manager Nuclear Medicine  
**from:** John Ramsey  
**subject:** NRC Inspection  
**date:** February 21, 2001

I have the evidence requested by Penny Lanzisera, Health Physicist, NRC.

Air Flow Checks: 1)Balancing Report by Bob Carl; 2) Xenon air concentration calculations by Jack Merkin.

Quality Management Program review for 1999. 2000 is in progress and will be furnished upon request.

Geometry test for the new dose calibrator CRC-15w.

Please understand no patient doses were assayed prior to January 9, 2001 on the CRC-15w. I was present, following the completion of the geometry test on 01/08/01, when the chief nuclear medicine technologist physically removed the CRC15R Rental, boxed it for return to Capintec, and placed the CRC-15w at dose preparation location.

The daily reminder for dose calibrator constancy was not edited to reflect this change of equipment. So, from 01/09/01 to 02/21/01 the daily constancy was performed on the new dose calibrator however the report shows this as the CRC-15r Rental. I made a comment for each daily constancy from 01/09/01 to 02/21/01 stating the actual dose calibrator used was the CRC-15w, Sn. 170135.

Please fax this memo, and supporting documents with a brief cover letter to Penny Lanzisera at Region I of the NRC. Fax 610-337-5269.

Thank you.

Hunterdon Medical Center  
HVAC Adjusting And Balancing Report

Prepared For

Hunterdon medical Center Safety Committee

By Bob Carl







Xenon air concentration calculations

O.1 Concentrations in Work Areas

- |                                     |                                     |
|-------------------------------------|-------------------------------------|
| current assumptions:                | assumptions in license application: |
| 1.a. 5 studies/week                 | 5 studies/week                      |
| b. 10 mCi/study                     | 20 mCi/study                        |
| c. 20% loss assumed                 | 25% loss assumed                    |
| d,e,f. (below)                      |                                     |
| g. MPC = 1 E-5 uCi/ml (restricted)  |                                     |
| MPC = 3 E-7 uCi/ml (non-restricted) |                                     |
| DAC = 1 E-4 uCi/ml (occupational)   |                                     |
| DAC = 5 E-7 uCi/ml (effluent)       |                                     |

2.a. Room	Supply(cfm)	Exhaust(cfm)	Difference
Camera 4	535	790	-255
Stress	635	700	-65
Camera 2	650	790	-140
Camera 1	580	680	-100
Hot Lab	235	480	-245
<b>Sum</b>	<b>2635</b>	<b>3440</b>	<b>-805</b>

2.b. Estimated average concentration in restricted areas:

For Camera Room 1:

$$\frac{10000 \text{ uCi} \times 5 \times 20\%}{680 \text{ ft}^3/\text{min} \times 28317 \text{ ml}/\text{ft}^3 \times 2400 \text{ min}/\text{wk}} = 2.16 \text{ E-7 uCi}/\text{ml}$$

For Hot Lab:

$$\frac{10000 \text{ uCi} \times 5 \times 20\%}{480 \text{ ft}^3/\text{min} \times 28317 \text{ ml}/\text{ft}^3 \times 2400 \text{ min}/\text{wk}} = 3.07 \text{ E-7 uCi}/\text{ml}$$

O.2. Effluent Concentrations in unrestricted areas

Assumptions used in license application:  
25 mCi released required 292 cfm

Current Assumptions:  
10 mCi x 5 patients/week x 20% loss = 10 mCi released  
680 cfm exhaust is available from Room 1 (alone)

For Camera Room 1:

$$\frac{10000 \text{ uCi} \times 5 \times 20\%}{680 \text{ ft}^3/\text{min} \times 28317 \text{ ml}/\text{ft}^3 \times 10080 \text{ min}/\text{wk}} = 5.15 \text{ E-8 uCi}/\text{ml}$$

Note: The activity released to the unrestricted areas would be the same as that released to the restricted areas, since no disposal is performed by (direct) release to the atmosphere. All unused activity is returned to the pharmacy or disposed via the trap. Only routine losses (20%) are vented to the atmosphere.

January 21, 2001

0.3. Monitoring of trap effluent

The trap is tested for charcoal saturation monthly according to manufacturer's instructions using the Xenalert.

The trap is tested weekly for constancy of response using a Cs-137 check source.

0.4. Spilled Gas Clearance Time

1.a. A, the highest activity of a single container: 20 mCi  
 b. (above 0.1.2.a.)

c. Q, the room exhaust (ml/min) = cfm x 28317 ml/cf

d. C, (DAC values above 0.1.1.g.)

e. V, volume of room 1 = 12'x20'x7' = 1680 ft<sup>3</sup> = 4.7 E+7 ml  
 room 2 = 12'x20'x7' = 1680 ft<sup>3</sup> = 4.7 E+7 ml  
 room 3 = 8'x20'x7' = 1120 ft<sup>3</sup> = 3.2 E+7 ml  
 room 4 = 12'x20'x7' = 1680 ft<sup>3</sup> = 4.7 E+7 ml  
 Hot lab = 8'x16'x7' = 896 ft<sup>3</sup> = 2.5 E+7 ml

2. Clearance time =  $-V/Q \times \ln(C \times V/A)$

Room	Control	Exhaust	Clearance time
Camera 1	Non-restricted	680 cfm	16 minutes
Camera 1	Restricted	680 cfm	3.5 minutes
Camera 2	Restricted	790 cfm	3.0 minutes
Camera 3	Restricted	700 cfm	3.0 minutes
Camera 4	Restricted	790 cfm	3.0 minutes
Hot Lab	Restricted	480 cfm	3.8 minutes

Conclusion

Xenon-133 concentrations in work areas and non-restricted areas are less than DAC values specified in 10CFR20 during routine use with normal losses. Spilled gas clearance times have been calculated. Instructions on room restrictions are posted.

The minimum required exhaust flow rates for each room where Xenon is used or stored:

For restricted areas (for worker doses): 1.5 cfm

For unrestricted areas (effluent): 70 cfm

January 21, 2001

*JSM*

MEMO

February 28, 2000

**To:** Radiation Safety Committee

**From:** Jack J. Merkin, Radiological Physicist *JJM*

**Subject:** Quarterly ALARA review (4th Quarter 1999)  
including review of the **Quality Management Program**

I have reviewed the personnel monitoring records of the nuclear medicine staff for the fourth quarter of 1999. All doses were less than the Investigational Level II limits (less than 30% of the Maximum Permissible Dose) and As Low As Reasonably Achievable. The MPD is 1250 millirem per quarter for the whole body, 12,500 millirem for extremities, and 3750 millirem per quarter for the eyes. The doses ranged from non-detectable to 150 millirem for the whole body, from non-detectable to 300 millirem for extremities, and from non-detectable to 280 millirem for the eyes. The elevated doses for the Cardio-vascular technologists reported last quarter persists, however, there has been insufficient time to evaluate if the recommendations have been effective. Also, one month's readings were elevated due to the control badge not being submitted.

Daily and weekly radiation surveys were also reviewed. Radiation levels were consistent with previous measurements, and no significant contamination events occurred this quarter. All areas had exposure, and contamination levels ALARA.

The written directives of all patients undergoing radio-pharmaceutical therapy or I-131 imaging in 1999 were reviewed. There were a total of 26 I-131 and Sr-89 administrations. There were no misadministrations or recordable events in 1999. Previous audits of the program are on file with the Radiation Safety Committee minutes. Results of the audits were presented to the Radiation Safety Committee. All aspects of the Quality Management program were also reviewed. No modifications to the program are recommended at this time.

HUNTERDON MEDICAL CENTER  
 NUCLEAR MEDICINE DEPARTMENT  
 FLEMINGTON, NEW JERSEY

GEOMETRY Report: 10-01-2000 to 02-20-2001

LIC. # NJ SL-70086

Date	Time	Test #	Dose Cal.	Serial #	Source	Configuration	Capacity	Std.Vol.	Trigger	Tech
10-10-00	16:05	3	CRC - 15R RENTAL	150968	Tc99m	Syringe	3.00ml	1.50ml	5.00 %	WS
10-10-00	16:07	4	CRC - 15R RENTAL	150968	Tc99m	Vial	20.00ml	8.00ml	5.00 %	WS
1-08-01	15:17	5	CRC-15W	170135	Tc99m	Vial	20.00ml	3.50ml	5.00 %	JR
1-08-01	15:29	6	CRC-15W	170135	Tc99m	Syringe	3.00ml	1.00ml	5.00 %	JR

the geometry tests have **PASSED**

Technologist Signature : \_\_\_\_\_

RSO Signature : \_\_\_\_\_

These Calibrators are required to be tested for Geometry Dependence upon installation, repair, or adjustment, and/or as otherwise specified by the radioactive materials license.



