

APPENDIX A NUCLEAR MEDICINE INSPECTION RECORD (IP 87115)									
REGION II									
Insp. Report #	00-01	License #	45-16618-01			Docket #	030-11338		
Licensee Name	HEALTHSOUTH Medical Center								
Street Address	7700 East Parham Road								
City, State, Zip	Richmond, Virginia 23294								
Location (Authorized Site) Being Inspected	7700 East Parham Road Richmond, Virginia 23294								
Licensee Contact Name		Jonathan Harrington, Director of Medical Imaging				Phone #	804-747-5681		
Priority	3	Program Code	2121		Description	Nuclear Medicine			
Date of Last Inspection:		9/26/96			Date of This Inspection		5/3/00		
Type of Insp.	Announced		Routine	X	Initial				
	Unannounced	X	Special						
Next Insp. Date	5/05	Normal		Reduced		Extended	X		
Justification for change in normal inspection frequency:		Meets criteria for extension in accordance with MC 2800-05.01.a.2 for increasing inspection frequency from 2 to 3 years (this inspection and previous inspection were 591 inspections)							
Summary of Findings and Actions									
No violations, Clear 591 or letter issued				X	Non-cited violations				
Violation(s), 591 issued		Violation(s), letter issued							
Follow up on previous violations:			N/A						
Inspector - Printed Name		Wade T. Loo							
- Signature		/RA/				Date	6/2/00		
Approved - Printed Name		Thomas R. Decker							
- Signature		/RA/				Date	6/2/00		

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
14	4/29/99	Add/Delete AUs; Change in RSO
13	4/22/97	Add/Delete Aus; Add two areas of use
2.	INSPECTION AND ENFORCEMENT HISTORY	
Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.		
1) 9/26/96: 591 Clear Inspection 2) 3/18 - 3/19/93: NOV - i) Failure to do daily surveys ii) Failure to do D. C. Constancy checks iii) Failure to have a quorum during RSC meeting		
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 identified since the date of the last onsite inspection. Also, a search of NMED did not identify any events associated with this facility.		
PART II - 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.

From a review of selected records from the date of the last onsite inspection and discussions with cognizant licensee representatives, the organization of the individuals involved in the use of licensed materials was found to be as follows:

- Chief Executive Officer (Chuck Stark)**
- Director of Medical Imaging (Jonathan Harrington)**
- Chief Nuclear Medicine Technologist (NMT) (Renee Knight)**
- 1 F/T NMT**
- 2 P/T NMTs**

During the onsite inspection, the inspector reviewed records and discussed those records regarding the scope of the licensee's radioactive material use program. From those reviews and discussions with cognizant licensee representative, the inspector determined that the licensee had utilized the services of a nuclear pharmacy for the delivery of unit doses for diagnostic and therapeutic patient studies. Licensed material was used in the NM Department and the Cardiovascular Office down the hall from NM. Those activities involved the use of 99m technetium (99m-Tc) labeled radiopharmaceuticals for routine nuclear medicine studies (lungs, livers, thyroids, heart, bone, sentinel node imaging, etc.) and Iodine 131 (I-131) for diagnostic and therapeutic patient studies. The number of patient studies was ~60 patients/week.

No violations or deviations were identified in this program area during the onsite inspection.

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.

Through discussions with cognizant licensee representatives and a review of selected records since the date of the last onsite inspection, the inspector determined that the RSO maintained oversight over all the licensed activities. However, the inspector found that the licensee depended on a consulting health physicist (CHP) (D. Broga) for conducting audits and reviews of the licensee's radiation safety program that included a review of records as well as the conduct of independent confirmatory radiation area and removable contamination surveys. From a review of the CHP's findings the inspector determined that the CHP was identifying few matters of noncompliance and had taken adequate actions to prevent recurrence.

Through further discussions and reviews, the inspector determined that the licensee had a Radiation Safety Committee (RSC) that included representatives from Nursing, Maintenance, Management, NM, and the RSO. From those reviews of records since the date of last onsite inspection and discussions, the inspector determined that the RSC met quarterly and reviewed matters that involved personnel radiation exposures, usage of specialized equipment, program audits, etc.

No violations or deviations were identified in this program area during the onsite inspection.

3.

FACILITIES

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

Through discussions with cognizant licensee representatives and direct observations, the inspector determined that the use of licensed material was maintained in two locations as described above in Section 1. During a tour of the NM Department, the inspector observed that NM consisted of one large imaging room and one hot lab. The imaging room was divided into two separate areas, each one with an imaging camera. Through further discussions and direct observations, the inspector determined that the hot lab was always locked when not in use. The inspector observed that the NMTs used a key to open the door to the hot lab each time they needed to gain access to that area. In addition, the inspector determined from those discussions that the nuclear pharmacy delivered radiopharmaceuticals during normal and off-work hours. If NM was not open the pharmacy driver would place the licensed material inside of the hot lab (driver had access to the key to the hot lab). In addition, the licensee maintained radwaste in the hot lab. The inspector observed that the radwaste was decayed to less than 10 half-lives and placed in the hospital trash. The inspector toured the cardiovascular area where radiopharmaceuticals were used for cardiac imaging studies. Licensee representatives informed the inspector that only radiopharmaceuticals were administered there and the patients would be sent to NM for concluding the study.

No violations or deviations were identified in this program area during the onsite inspection.

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.	
<p>During the onsite inspection, the inspector reviewed the licensee's controls for the use of licensed materials at their facilities. As discussed above in Section 3, the inspector found that the licensee had maintained adequate controls to prevent the unauthorized removal of licensed materials in all areas where such material was being used or stored. Furthermore, the inspector reviewed records of radiopharmaceutical receipts and transfers between them and the nuclear pharmacy and discussed those records with cognizant licensee representatives. From those reviews and discussions, the inspector found the licensee's controls adequate for the use of licensed materials at their facilities.</p> <p>No violations or deviations were identified in this program area during the onsite inspection.</p>	
6.	RADIOPHARMACEUTICAL THERAPY
Safety precautions; surveys; and release criteria of patients and rooms.	
<p>Through discussions with cognizant licensee representatives, a review of selected records since the date of the last onsite inspection, and direct observations, the inspector determined that the licensee used I-131 in capsule form for diagnostic and therapeutic purposes, strontium-89, and samarium-153. The licensee conducted ~ 5, 2, and 1 outpatients/year, respectively. From those discussions and reviews, the inspector determined that the licensee conducted those therapies in accordance with NRC regulatory requirements.</p> <p>No violations or deviations were identified in this program area during the onsite inspection.</p>	
7.	QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS
QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records.	

During the onsite inspection, the inspector discussed with cognizant licensee representatives the licensee's QMP and reviewed selected records since the date of the last onsite inspection. From those reviews and discussions the inspector determined that the licensee conducted an annual review of the QMP. The inspector did not identify any misadministrations from a review of selected records since the date of the last onsite inspection and discussions with cognizant licensee representatives during the onsite inspection.

No violations or deviations were identified in this program area during the onsite inspection.

8.

AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

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

During the onsite inspection, the inspector reviewed selected area radiation and removable contamination surveys that had been conducted for all areas where licensed material was being used or stored since the date of the last onsite inspection as well as other controls used by the licensee to reduce contamination. In addition, the inspector reviewed selected leak test and inventory records of sealed sources that had been conducted since the date of the last onsite inspection. From those reviews of records and discussions of those records with cognizant licensee representatives, the inspector determined that the licensee had conducted such surveys and inventories in accordance with NRC regulatory requirements for the licensed materials used at the licensee's facility.

No violations or deviations were identified in this program area during the onsite inspection.

9.

TRAINING AND INSTRUCTIONS TO WORKERS

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

Through discussions with cognizant licensee representatives and a review of selected training records since the date of the last onsite inspection, the inspector determined that ancillary personnel (i.e. - housekeeping, security, maintenance) were given annual refresher training because they would interact with patients or areas where licensed materials were used or stored. The training consisted of a videotape that included the hazards associated with radioactive materials. Through further discussions, the inspector was informed by cognizant licensee representatives that such staff did not have access to the hot lab (hot lab trash) and were only authorized to be cleaning in the area during normal NM working hours. In addition, the inspector determined that Operating Room personnel were given radiation safety training specific for patients undergoing sentinel node imaging studies.

No violations or deviations were identified in this program area during this onsite inspection.

10.

RADIATION PROTECTION

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

Through discussions with cognizant licensee representatives, a review of selected dosimetry records since the date of the last onsite inspection and direct observations, the inspector determined that the RSC reviewed personnel radiation exposure records as discussed above in Section 2. In addition, the inspector determined that the licensee utilized radiation personnel dosimeters (Landauer, Inc.) that were NVLAP approved that included dosimeters for measuring whole body and extremity exposures. From those reviews of selected dosimetry records the inspector found the following results as expressed in millirem:

<u>Year</u>	<u>Annual</u>		<u>Quarter</u>	
	<u>Whole Body</u>	<u>Extermity</u>	<u>Whole Body</u>	<u>Extermity</u>
1997	230	1,690	100	750
1998	170	1,970	70	660
1999	327	2,350	126	910
2000 - Not available at the time of the onsite inspection				

No violations or deviations were identified in this program area during this onsite inspection.

11.	RADIOACTIVE WASTE MANAGEMENT
<p>Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records.</p>	
<p>During the onsite inspection, the inspector reviewed with cognizant licensee representatives the management of radioactive waste from their facility. From discussions, reviews of selected records since the date of the last onsite inspection and direct observations of the radwaste storage area, the inspector determined that the licensee disposed of used radiopharmaceutical syringes and other medical supplies that could have been possibly contaminated from the use of radiopharmaceuticals. The inspector observed that the licensee stored the waste in the hot lab in appropriately shielded containers for decay-in-storage. From those discussions and reviews, the inspector determined that after 10 half-lives had passed the licensee disposed of the waste as normal trash or handled it as biohazard waste.</p> <p>No violations or deviations were identified in this program area during this onsite inspection.</p>	
12.	DECOMMISSIONING
<p>Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements.</p>	
<p>Through discussions with cognizant licensee representatives and a review of records since the date of the last onsite inspection, the inspector did not identify any areas located at the licensee's facilities that had been decommissioned.</p>	
13.	TRANSPORTATION
<p>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.</p>	

Through discussions with cognizant licensee representatives, a review of selected records since the date of the last onsite inspection and direct observations, the inspector determined that the licensee used the services of a nuclear pharmacy as discussed above in Section 1. Also, as discussed above in Section 3, the inspector determined that the nuclear pharmacy delivered radiopharmaceuticals primarily during normal and off hours at the hospital. Licensee representatives informed the inspector that any unused radiopharmaceuticals were returned to the pharmacy during the next run. However, used syringes were disposed of in a lead lined trash cans for decay-in-storage as discussed above in Section 11. The inspector observed a container that the nuclear pharmacy used to transport radiopharmaceuticals and found it be to adequate to ensure compliance with NRC and DOT regulatory requirements. Based on those discussions and reviews, the inspector determined that no other RAM had been transported to or from the licensee's facility.

No violations or deviations were identified in this program area during the onsite inspection.

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.

During the onsite the inspector reviewed and discussed with cognizant licensee representatives, any incidents that may have involved theft or loss of radioactive materials, overexposures of individuals, and radiation exposure reports to individuals. From those discussions and reviews of selected records since the date of the last onsite inspection and a search of NMED, the inspector did not identify any concerns in this program area since the date of the last onsite inspection.

No violations or deviations were identified in this program area during the onsite inspection.

15.

POSTING AND LABELING

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

During the onsite inspection, the inspector toured the licensee's facilities and observed appropriate RAM signs on the Hot Lab door, the entrance to the NM department, cabinet doors and trash cans. In addition, the inspector observed that the licensee had posted an appropriately placed NRC Form 3 in various areas as well as notices indicating where other appropriate documents related to the license could be found for review.

No violations or deviations were identified in this program area during this onsite inspection.

16.

INDEPENDENT AND CONFIRMATORY MEASUREMENTS

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

During the onsite inspection the inspector conducted independent confirmatory area radiation surveys of the NM department and the Cardiovascular Office to include the hot lab, imaging rooms, and adjacent rooms to NM using the following instrument:

<u>Manufacturer</u>	<u>Model Number</u>	<u>Serial Number</u>	<u>Calibration Date</u>
Ludlum	2401-P	145165 (NRC Tag No. 067664)	8/23/99

From those independent confirmatory radiation survey measurements, the inspector did not identify any radiation levels that exceeded any NRC regulatory limits, areas were found to be posted in accordance with NRC regulatory requirements, and results were similar to those of the licensee's.

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.

During the onsite inspection, the inspector did not identify any violations or deviations of NRC regulatory requirements (NRC Form 591 Clear).

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
#*Jonathan Harrington *Scott Hill Renee Knight Chrissandra Smith	Director of Medical Imaging Assistant Administrator Nuclear Medicine Supervisor Nuclear Medicine Technologist	804-747-5681 804-747-5636 804-747-5636	In Person In Person In Person In Person
19.	PERFORMANCE EVALUATION FACTORS		
A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.	Y	N X
B.	RSO too busy with other assignments.	Y	N X
C.	Insufficient staffing.	Y	N X
D.	RSC fails to meet or functions inadequately.	N/A	Y N X
E.	Inadequate consulting services or inadequate audits conducted.	N/A	Y N X
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.)			
Based on discussions with cognizant licensee representatives, a review of selected records since the date of the last onsite inspection, and direct observations, the inspector found that the licensee's oversight of the radiation safety program was adequate for ensuring compliance to NRC regulatory requirements.			
20.	SPECIAL CONDITIONS OR ISSUES		
NONE	X	Special license conditions; year-2000 effects of computer software.	
None were identified during the onsite inspection.			
PART III - POST- INSPECTION ACTIVITIES			
1.	REGIONAL FOLLOWUP ON PEFs		
Not Applicable, No concerns were noted during the onsite inspection.			

2.	DEBRIEF WITH REGIONAL STAFF
<p>Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.</p>	
<p>After conducting the onsite inspection, the inspector debriefed the MLIB1 Branch Chief of the inspection findings.</p>	
3.	YEAR-2000 ISSUES
<p>Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.</p>	
<p>Not Applicable to the program areas conducted during this onsite inspection.</p>	

TO ADVANCE TO NEXT SECTION OF FORM - PUSH PAGE DOWN KEY

**APPENDIX A - ATTACHMENT A
DECOMMISSIONING TIMELINESS INSPECTION ATTACHMENT**

Licensee:	HEALTHSOUTH Medical Center	Date of Inspection:	5/3/00
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1. COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE

(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)

A.	License to conduct a <i>principal activity</i> <u>has</u> expired or been revoked:	Y		N	X
B.	Licensee <u>has</u> made a decision to permanently cease <i>principal activities</i> at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds:	Y		N	X
C.	A 24-month duration has passed in which no <i>principal activities</i> have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds:	Y		N	X
D.	If "Yes" to either A or B or C above:				
(1)	Identify Site/Bldg./Area:				
(2)	Date of occurrence of A, B, or C:				

2. NOTIFICATION REQUIREMENTS

A.	Licensee has provided written notification to U.S. NRC within 60 days of the occurrence of 1.A., 1.B., or 1.C. above.	Y		N	
If "Yes," date of notification:					
B.	If the licensee is requesting to delay initiation of the decommissioning process, the licensee <u>has</u> provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C. above:	N/A	Y	N	
If "Yes," date of notification:					

Basis for Findings:

3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS

A.	Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72?	N/A	Y	N	
If "No" to 3.A., answer the following items B - F:					

B.	The decommissioning work scope is covered by current license conditions.	Y		N	
C.	Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay.	Y		N	
D.	If licensee has initiated decommissioning, give date the decommissioning was initiated:				
E.	If decommissioning has been completed, it was completed within 24 months of notification to NRC.	N/A	Y	N	
F.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification to NRC.				
		N/A	Y	N	
Basis for Findings:					
If "Yes" to 3.A., answer the following items G - J:					
G.	The decommissioning plan has been submitted to NRC within 12 months of notification.	Y		N	
If "Yes," date of submittal:					
If NRC approved, date of NRC approval:					
H.	Has the licensee submitted an alternative schedule request?	Y		N	
If "Yes," date of submittal:					
I.	If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan.	N/A	Y	N	
J.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.				
		N/A	Y	N	
Basis for Findings:					
Violations identified, if any:					

END