REPORT NUMBER(S) **00-01**	**ATLANTA FEDERAL CENTER** **61 FORSYTH ST SW STE 23T85** **ATLANTA, GA 30303-3415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-32086	**45-25136-01**	**November 15, 2000**

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.

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			
NRC INSPECTOR	**Richard Gibson, Jr.**	**\RA**	**11/21/00**

APPENDIX A NUCLEAR MEDICINE INSPECTION RECORD (TEMPORARY INSTRUCTION 2800/029)												
REGION **II**												
Insp. Record #	**00-01**	License #	**45-25136-01**	Docket #	**030-32086**							
Licensee Name	**Stonewall Jackson Hospital**											
Street Address	**Spotswood Road**											
City, State, Zip	**Lexington, Virginia 24450**											
Location (Authorized Site) Being Inspected	**same as above**											
Licensee Contact Name	**Paul G. Faucher, M.D., RSO**			Phone #	**540-462-1350**							
Priority	**03**	Program Code	**02120**	Description	**Medical Institution (QMP required)**							
Date of Last Inspection:	**8/23/95**			Date of This Inspection	**11/15/00**							
Type of Insp.	Announced		Routine	**X**	Initial							
	Unannounced	**X**	Special									
Next Insp. Date	**11/05**	Normal		Reduced		Extended	**X**					
Justification for change in normal inspection frequency:	**The extension in the inspection frequency is in accordance with MC 2800. The last inspection dated August 23, 1995, did not identify violations of NRC requirements. This inspection dated November 15, 2000, also did not identified violations of NRC requirements. There were no significant changes of personnel to the radiation safety program.**											
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:												
Inspector - Printed Name	**Richard Gibson, Jr., Health Physicist Materials Licensing/Inspection Branch 1**											
- Signature		Date	**11/29/00**									

Approved - Printed Name	**Thomas R. Decker, Chief Materials Licensing/Inspection Branch 1**		
- Signature		Date	12/08/00

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

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

Last inspection conducted on August 23, 1995 - Clear NRC Form 591 issued. The inspector identified one NCV during the last inspection which involved records of radioactive waste disposal surveys not recorded; however, the licensee did indicate that surveys were performed.

5. 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 event's database, regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

A review of the license file, a search on NMED and an interview with cognizant licensee personnel indicated no incidents, recordable events, or misadministrations reported to the NRC since the last inspection.

PART II - INSPECTION DOCUMENTATION

The inspection documentation part is to be used by the inspector to assist with the performance of the inspectionl lote that all focus elements are to be addressed durinl each inspectionl

lll areas colered durinl the inspection should be documented in sufficient detail to describe what actilities and procedures were obserled andlor demonstratedl ln additionl the types of records that were reliewed and the time periods colered by those records should be notedl lf the licensee demonstrated any practices at your reluestl describe those demonstrationsl The obserlations and demonstrations you describe in this reportl alonl with measurements and some records reliewl should substantiate your inspection

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)

   Stonewall Jackson Hospital organization is staffed with Robert Hutch as the Hospital Administrator/CEO; Mary Ann White is the Director of Radiology; and Paul G. Faucher, M.D., is the Radiologist and the Radiation Safety Officer. In nuclear medicine, the organization is staffed with Clark Mooney as the Nuclear Medicine Technologist; and Barry Armentrout as the Radiology Technologist. The licensee contracts with Lee Anthony, Ph.D., from Physics Associates as their consultant.

   The licensee conducted diagnostic imaging to patients by administering technetium-99m for primarily cardiac, bones, lung and gall bladder scans. On occasion, the licensee had administered iodine-123 for thyroid uptake. The licensee administered radiopharmaceutical for diagnostic imaging to 3 to 4 patients per day. During this inspection, the inspector determined through discussion with the licensee and review of records that the licensee had not conducted any therapy procedures since the last inspection with iodine-125 or 131.

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

   Robert Hutch, Administrator/CEO
   Mary Ann White, Director of Radiology
   Paul G. Faucher, M.D., Radiation Safety Officer
   Clark Mooney, Nuclear Medicine Technologist

   All personnel were contacted in person by the inspector.

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

The inspector performed a radiation survey and a contamination survey in the general areas of nuclear medicine and on the surface of waste containers and storage areas in the hot laboratory. Radiation measurements indicated < 0.1 mr/hr, and contamination measurements indicated < 2000 dpm/100 cm². Instrument used for the survey by the inspector was a Ludlum Model 2401-P, NRC S/N 065625, calibrated on March 17, 2000. The inspector determined based on independent radiation and contamination measurements, the licensee met the NRC requirements for unrestricted areas.

The inspector evaluated the licensee's survey procedures through reviewing the daily radiation survey and weekly contamination survey records of the facility for the period November 15, 2000 to January 1996. The inspector determined that the records were as required by the NRC requirements, and that the licensee used material as required by the license.

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

During the tour of the facility, the inspector noted the appropriate postings. The postings included NRC Form-3, documents regarding where information of the regulations may be found, a copy of the license and "CAUTION: RADIOACTIVE MATERIAL", signs on the entrance to nuclear medicine and proper labels on containers and equipment containing radioactive material.

PART III - FOCUS ELEMENTS

1. ADEQUATE PROGRAM SURVEILLANCE AND CORRECTIVE ACTIONS: (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)

Yes	X	No	

The inspector interviewed the RSO and the NMT and reviewed records to evaluate management and the RSO support and oversight of the radiation safety program. The inspector determined that the licensee established a Radiation Safety Committee that meets every year to provide support to the radiation safety program. Records of the RSC minutes were reviewed by the inspector for the period October 17, 2000 to January 29, 1996. The RSC did not identified any safety problems since the last inspection. The inspector determined from discussion with the licensee and review of records that their consultant, Lee Anthony, Ph.D., from Physics Associates and the RSO, conducts quarterly audits, and annual review of the radiation safety program. The inspector reviewed the records of the quarterly audits for the period October 16, 2000 to January 29, 1996. Records of annual review of the radiation safety program were reviewed by the inspector for the period April 17, 2000 to July 12, 1996. There were no significant safety issues identified by the consultant.

The inspector determined, based on interviews with licensee personnel, observations and review of records, that the RSO and management adequately oversees the radiation safety program through the RSC and their consultant. In addition, the inspector determined from the review of records and discussion with licensee personnel, that the ALARA procedures were adequate.

2. KNOWLEDGEABLE STAFF AND MANAGEMENT: (Use by qualified and knowledgeable individuals; safe work practices; all levels of management possess sufficient knowledge to provide effective oversight of the program)

Yes	X	No	

The inspector interviewed the NMT and RSO, and reviewed training records to evaluate the staff knowledge and work practices in nuclear medicine. The inspector determined that the staff received annual refresher radiation safety training provided by their consultant. In addition, the consultant provided updated material regarding NRC regulations during quarterly audits of the radiation safety program. The inspector observed the NMT demonstrated the administration of radiopharmaceutical to a patient and the proper handling and disposal of the radioactive waste. The inspector also observed the NMT demonstrated the use of a survey instrument for measuring contamination and radiation. The inspector determined that the NMT used good work techniques in preparing and administering radiopharmaceutical to patients, and in performing adequate surveys.

3. OCCUPATIONAL AND PUBLIC DOSES WITHIN REGULATORY LIMITS: (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)

Yes	**X**	No	

The inspector reviewed the licensee's program for monitoring occupational and public doses to assess whether the licensee's radiation protection program included ALARA provision. Based on discussions with the licensee staff, the inspector determined that the licensee did not have any off site contamination events or any major contamination in nuclear medicine. The inspector reviewed radiation exposure records for the period October 30, 2000 to January 4, 1996. The inspector verified that the staff in nuclear medicine was issued and wearing personnel dosimetry while handling licensed material, and that the licensee exchanged dosimetry at the required monthly frequency. The personnel dosimeters were exchanged by Landauer (Luxel) monthly. The maximum whole body exposure observed by the inspector was 70 mrem and 260 mrem for the extremity exposure. The inspector reviewed the patient's dose records for the period October 31, 2000 to January 1996. The records were as required by NRC and the license requirements. During the tour of the hot lab, through observation and discussions with the NMT, the inspector determined that the licensee possesses syringe shields and syringe pigs for the handling of radiopharmaceutical during administration to patients.

The licensee's program for monitoring occupational and public exposures met regulatory requirements. The inspector determined that the licensee was maintaining personnel radiation exposures and dose to patients ALARA and that no NRC regulatory radiation exposure limits had been exceeded.

4. ADEQUATE SECURITY AND CONTROL OF LICENSED MATERIAL: (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)

Yes	**X**	No	

During this inspection, the inspector determined through discussions with the licensee and review of records that the licensee primarily possessed and used Tc-99m for diagnostic imaging to patients. The licensed material was used and stored in the hot lab of nuclear medicine. The inspector observed that the licensee maintained adequate security of the radiopharmaceutical and sealed sources in the hot lab area of nuclear medicine, and that the hot lab remained secured when not occupied by the staff. Leak tests and inventories of the sealed sources were conducted by the licensee's consultant at every quarter. The inspector reviewed the records for the period October 16, 2000 to January 29, 1996. The records were as required by NRC requirements. Sealed sources possessed by the licensee were: a cobalt-57 source containing 429 microcuries, a cesium-137 source containing 213.1 microcuries, and a barium-133 source containing 148.7 microcuries.

Package containing radiopharmaceutical were delivered to the licensee during the early morning hours and during normal business by their supplier Blue Ridge Pharmacy. The supplier has key access to nuclear medicine and the hot lab during the early morning hours. The NMT conducts the receipt surveys of the packages upon arrival to nuclear medicine. Records of package receipt, incoming, were reviewed by the inspector for the period November 15, 2000 to January 1996. The records were as required by NRC requirements.

Through discussions with the NMT and from the review of the radioactive waste disposal records, the inspector evaluated whether the licensee disposed of radioactive waste in accordance with NRC requirements. The inspector determined that the licensee stored the used syringes and solid radioactive waste for decay-in-storage by holding the waste for 10 half-lives. The inspector reviewed records of radioactive waste disposal survey for the period October 2000 to January 1996. The inspector determined from the review that the NMT performed the required surveys and removed the labels after the decay of the waste. The inspector determined that the licensee disposed of radioactive waste safely and in accordance with NRC requirements.

5. USE OF LICENSED MATERIAL ONLY AS AUTHORIZED: (Authorized users, uses, types and quantities of materials, and locations; adequate supervision by authorized users)

Yes	**X**	No	

The inspector interviewed the NMT and reviewed patient dose records, and determined that the licensee used licensed materials as authorized on the NRC license and what was prescribed by the authorized user. The inspector also determined that adequate supervision by the RSO was provided to the staff in nuclear medicine for the use of licensed material. The licensee had not performed any procedures since the last inspection, for the therapy administration of radiopharmaceutical.

The licensee along with the service of the consultant conducted several quality control tests on the dose calibrator (an AtomLab 100, S/N 588007) to ensure accurate measurement of the unit dosages prior to the administration to patients. The inspector reviewed records of daily constancy for the period November 15, 2000 to January 5, 1996, and of quarterly linearity for the period October 11, 2000 to January 18, 1996. Records of annual accuracy were reviewed by the inspector for the period October 16, 2000 to July 24, 1996. The records were as required by NRC requirements.

6. RADIOPHARMACEUTICAL ADMINISTRATIONS CONFORMING TO THE PHYSICIAN'S WRITTEN DIRECTIVES: (Quality management program - written directives, implementation, reviews; Misadministrations - identification, notifications, reports, and records)

Yes		No	

This section was not applicable during the time of the inspection.

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)

The inspector informed his branch chief of the inspection findings. There were no licensing action outstanding during the time of this inspection.

2. OTHER: