NRC FORM 591 PART 1
(8-1997)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
Citizens Memorial Hospital Bolivar, MO 65613 REPORT NUMBER(S)	REGION III US NUCLEAR REGULATORY COMMISSION 801 WARRENVILLE ROAD LISLE IL 60532-4351

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-35632	24-20330-02	June 28, 2001

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		GLS	7/19/01
NRC INSPECTOR	Robert P. Hays		6/28/01

INSPECTOR

APPENDIX A
NUCLEAR MEDICINE INSPECTION RECORD
Region III

Inspection Report No. **2001-001** License No. **24-20330-02**
Licensee (Name & Address): Docket No. **030-35632**

Citizens Memorial Hospital
1500 No. Oakland
Bolivar, MO 65613-3099

Location (Authorized Site) Being Inspected: **1500 No. Oakland, Bolivar, Missouri**

Licensee Contact: **Charlotte Thurman, CNMT** Telephone No.: **417/326-6000**

Priority: **G-5**
Program Code: **02220**

Date of Last Inspection: **Not applicable**
Date of This Inspection: **June 28, 2001**

Type of Inspection:				
	(✔)	Announced	( )	Unannounced
	(✔)	Routine	( )	Special
	(✔)	Initial		

Next Inspection Date: **July 2006** (✔) Normal ( ) Reduced ( ) Extended

Justification for change in normal inspection frequency:

Not applicable.

Summary of Findings and Actions:

(✔) **No violations cited, clear NRC Form 591 issued**
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: _____ Date: **July 12, 2001**
(Signature)
Robert P. Hays, Health Physicist

Approved : _____ Date 7/15/01
(Signature)
Gary L. Shear, Chief, MIB

A review of the licensed activities should be commensurate with the scope of the licensee's program. A determination regarding safety and compliance with requirements will be based on direct observation of work activities; interviews and discussions with workers and management; demonstrations by workers performing tasks regulated by NRC; and independent and confirmatory measurements of radiation conditions at the facility rather than exclusive reliance on a review of records. Under no circumstances will an NRC Inspector knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent and unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy. Discussion of the inspector's observations of work activities with the workers and interviews with the workers should not occur during the preparation for, or delivery of medical treatment. Inspector's interviews should not be conducted in the presence of the patient.

In reviewing the licensee's performance, the inspector should cover the period since the last inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

Specific inspection requirements follow; however, some of the areas may not be applicable to all nuclear medicine licensees.

Preparation. Before the inspection, the inspector shall do the following:

__✓__ Review the licensee's licensing history, including identifying any amendments issued since the last inspection, pending licensing actions, and whether the licensee has informed NRC of any major program changes since the last inspection.

__✓__ Review the licensee's previous inspection history (at a minimum, review the past two inspections); the license; and the status of any allegations or incidents. Note the licensee's commitments in response to previous violations for follow-up during the inspection.

__✓__ Review the Nuclear Materials Events Database (NMED) and any regional event logs and files to determine whether the licensee was involved in any incidents, recordable events, or misadministrations. If NRC did receive notification of an incident, review that incident during the inspection and document the licensee's follow-up in the inspection record.

__N/A__ Preparation should also include determining the dates that the licensee submitted the most recent financial assurance instrument and decommissioning plan (if applicable); notifying the appropriate State radiation control program personnel; and selecting appropriate documents and equipment to take. In addition, the appropriate calibrated instruments should be selected and source checks performed on them before the inspection.

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

No amendments to the license have occurred since the license was issued on JAN 25 2001.

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

Not applicable.

3. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations 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".

This licensee has not had any fires, explosions, fatalities, lost/stolen radioactive material, over exposures, misadministrations/recordable events, package contamination exceeding DOT limits, or any other reportable event since the license was issued on JAN 25 2001. See attached NMED inquiry.

NMED

Nuclear Materials Events Database

Click on the Browser's 'Back' Button at the top left of the screen to return to the previous page.

These are your Selected Query Options:

Licensee Name/License Number: 24-20330-02	**Reporting Requirement:** All names and numbers are included
State(s): All States are included	**Isotope:** All Isotope are included
Event Cause: All Causes are included	**Keyword:** All Key Words are included
System Involved: All Systems are included	**Date Range:** 01/01/1989 to 06/21/2001
Component Involved: All Components are included	**NRC Region(s):** 0 1 2 3 4
Reportable Events: All States: Reportable, Not Reportable and Unknown	**Event Classes Included:** All Event Classes are Included
Agreement State Status: All States: Agreement or Not	**Abnormal Occurrence Status:** All Occurrence: Abnormal or Not
Sorted By: Licensee Name	

No Records Found.

NMED Home | Report Menu

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 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 all areas indicated in this part are not 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.

__✓__ ***Entrance Briefing***. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site.

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)

__✓__ ***Organization***. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management; the Radiation Safety Officer (RSO); the Chairperson of the Radiation Safety Committee (RSC); and the other members of the RSC. Determine whether the RSO has sufficient access to licensee management. Through discussions with licensee staff and management, the inspector should determine if changes in ownership or staffing have occurred or are anticipated to occur. Confirm (to the inspector's satisfaction) with personnel that no changes have taken place. If the owner or individuals named in the license have changed, determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel are made.

__✓__ ***Scope of Program***. Interview cognizant personnel to determine the locations of use, types and quantities of licensed byproduct material used for medical uses, frequency of use, staff size, and any other factors, as necessary, to determine the scope of the licensee's operations.

N/A If a mobile nuclear medicine program is being inspected, information concerning letters of contract with the licensee's client management should be discussed and reviewed.

N/A Determine if the licensee conducts research involving human subjects using byproduct material. If so, verify that the licensee obtains informed consent from the human subjects and that the licensee has obtained prior review and approval of the research activities by an "Institutional Review Board."

Tim Johnson, COO
↕
Greg Elliott, Director of Radiology
↕
Richard Reber, MD, RSO, authorized user (AU)
↕
Nuclear Medicine Technologist

The NMTs routinely perform 1-2 administrations per day for routine bone, lung and other routine diagnostic and imaging studies. The majority of studies involve bone scans. The RSO is available each day at the hospital. The NMT's work and use of licensed material will be audited quarterly by the licensee's consultant. No I-131 used. The licensee receives unit doses from a nuclear pharmacy in Springfield, MO. Licensed activities began on March 19, 2001. Staff consists of one NMT, and one authorized user.

Within the areas inspected, no violations of NRC requirements were identified.

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 Oversight.*** In the course of interviewing cognizant personnel, determine if management oversight is sufficient to provide the licensee staff with adequate resources and authority to administer the licensed program. In particular, the inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, to implement corrective actions, including termination of operations that pose a threat to health and safety.

✓ ***RSC.*** Review the committee meeting minutes for topics of discussion, membership, frequency, and attendance. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector should also review the meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

✓ The inspector should interview some RSC members to determine the depth of their involvement in the radiation safety program.

✓ ***RSO.*** Determine whether the RSO has been appointed, is named on the license, has

sufficient authority, and fulfills the appropriate duties commensurate with the size and scope of licensed activities. The inspector should verify that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations.

___✓___ ***Audits.*** At a minimum, medical institution licensees are required, by 10 CFR 35.22(b)(6), to review the radiation safety program content and implementation at least annually. Verify that audits are performed as required. Verify that the results of the audits are documented, reviewed, and addressed. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements. **No audits required as of the date of the inspection.**

___✓___ ***ALARA (As Low As Is Reasonably Achievable)*** - Verify that the licensee's radiation protection program includes provisions for keeping doses ALARA and that ALARA reviews are conducted, as required by 10 CFR 35.2.

___✓___ ***Authorized Individuals.*** Determine that only authorized individuals (users and nuclear pharmacists) perform and/or supervise licensed activities. Verify that authorized individuals perform an appropriate level of supervision, as required by 10 CFR 35.25.

The licensee conducts monthly radiation safety committee meetings. RSC meeting minutes indicated that meetings were held 5/30/01, 4/25/01, and 3/12/01. Committee membership meets NRC requirements. Meeting minutes included NRC-required subject discussions and other business matters.

Within the areas inspected, no concerns for management oversight or violations of NRC requirements were identified.

3. FACILITIES:
(Facilities as described; uses; control of access; and engineering controls)

___✓___ ***Walk-Through Orientation Tour.*** Perform a walk-through tour of the licensed facility to make general observations of the condition of the facility and the licensed activities to determine that materials are being safely handled and that good health physics practices are followed.

___✓___ ***Facilities.*** Verify that the facility conforms to that described in the license application and that material receipt, use, and storage areas are secured. Verify that the licensee uses process or other engineering controls to maintain doses ALARA and has implemented a maintenance program for the engineering controls.

The licensee's facility is as described in the license amendment which had prior NRC approval. Security of licensed material in the hot lab and scanning areas was observed by the inspector to be adequate.

Within the areas inspected, no violations of NRC requirements were identified.

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.)

__✓__ Verify that equipment and instrumentation are appropriate, operable, properly calibrated, adequately maintained, and conform to the scope of the licensed program.

__✓__ Verify that, if molybdenum-99/technetium-99m generators are utilized, the licensee measures the molybdenum-99 concentration of each eluate/extract used for preparing a technetium-99m radiopharmaceutical and limits usage to those eluates/extracts with <0.15 microcuries of molybdemum-99 per millicurie of technetium-99m.

__✓__ Verify that vials and syringes are properly labeled and shielded.

__✓__ Verify that the licensee has established and implemented procedures to identify, evaluate, and report safety component defects per the requirements of 10 CFR Part 21.

__✓__ If gamma-emitting unit doses supplied by a licensed radiopharmacy are used, ensure the licensee measures the activity of each syringe and compares it with the activity marked on the syringe label before the dose is administered to a patient.

The licensee possesses a Capintec CRC 15R, s/n 154415, dose calibrator. Required dose calibrator tests were performed prior to initial patient scans on 2/23-24/01. A random review of dose calibrator constancy test records for March 2001 through June 2001 indicated that tests are performed each day prior to use, using Cs-137 and Co-57 check sources. The most recent linearity test was conducted on 5/11/2001. Initial linearity test activity was 160 mCi and tested down to 25μCi, with linearity error less than 3%. Accuracy tests are performed as required by the consultant with the most recent test record available was performed 2/24/01 and test results indicated - .7% error for cesium-137, -3.3% for barium-133, and -2.3% for Co-57, and 0.0 % for Co-60 indicating acceptable accuracy test results.

The licensee has calibrated Ludlum Model 14C survey meter, s/no. 172283. The inspector determined through observation that syringe shields, gloves, protective clothing, and dosimetry were available and were being used.

Within the areas inspected, no violations of NRC requirements were identified.

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)

__✓__ ***Authorized Uses***. Determine, from observing the use of licensed material, discussing the activities with licensee personnel, and reviewing records of receipt and transfer, that the type, quantity, and use of licensed material at the licensee's facility are authorized by the license. To the extent practical, physically examine the licensee's inventory of

radioactive material to determine if it is complete and accurate, and review the licensee's receipt and transfer records.

✓ ***Material Security and Control.*** Verify that the licensee has established procedures for maintaining security and control of licensed material, and that these procedures are understood and implemented by appropriate personnel. Verify that licensed material, in storage, in controlled or unrestricted areas, is secure from unauthorized removal or access. Verify that licensed material, not in storage, in controlled or unrestricted areas, is controlled and under constant surveillance. Verify that access to restricted areas is limited by the licensee.

✓ ***Receipt and Transfer of Licensed Material.*** Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Licensed material use is as authorized. The majority of waste is returned to the nuclear pharmacy. Packages are delivered to the hot lab by the vendor. Packages are surveyed and wipe tested as required with results documented. The inspector determined through interview of the NMT and a review of receiving records that there had been no occurrences where any packages received had elevated contamination results or elevated survey results. Package wipe tests are counted using a Ludlum 2200 well counter system.

Within the areas inspected, no violations of NRC requirements were identified.

6. RADIOPHARMACEUTICAL THERAPY:
(Safety precautions; surveys; and release criteria of patients and rooms.)

No I-131 used by the licensee.

7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS:
(QMP-written directives, implementation, reviews, and records; misadministrations-identification, notifications, reports, and records)

N/A **Written QMP**. Verify that a written QMP, commensurate with the licensee's activities, has been established and implemented. Also, verify that the QMP procedures address all of the applicable modalities on the license and all of the applicable objectives set forth in 10 CFR 35.32.

N/A ***Review.*** Verify that the licensee has reviewed the QMP at least annually. If the reviews indicated that changes should be made in the QMP program, verify that such modifications were made and implemented.

N/A ***Records.*** Verify that records of each review are maintained in an auditable form for 3 years.

N/A ***Misadministrations and Recordable Events.*** Through review of the licensee's

records, determine if the licensee is in compliance with the requirements for identification, notification, reports, and records for misadministrations and recordable events in 10 CFR 35.33.

The licensee does not use any radiopharmaceuticals that requires a QMP to be implemented. A negative declaration was included with the license application.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses)

✓ ***Area Surveys.*** Verify, during observations and by direct measurements, that the radiation levels are within the limits of 10 CFR Part 20, and that surveys are performed, as required by 10 CFR 35.70. Verify that the licensee has established trigger levels and that the licensee decontaminates at the appropriate trigger levels.

✓ ***Leak Tests.*** Verify that the procedures for and frequency of leak tests of sealed sources are in accordance with 10 CFR 35.59(b)(2). Also verify that the leak test is analyzed in accordance with the license. If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels), verify that the licensee made appropriate notifications per 10 CFR 35.59(e) and removed the source from service.

✓ ***Contamination Control.*** Verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. Verify that the licensee performs weekly surveys for removable contamination in all areas where radiopharmaceuticals are routinely prepared, administered, or stored. If the licensee has had spills or other incidents of contamination exceeding the licensee's trigger levels, verify that the licensee has taken appropriate actions.

✓ ***Protective Clothing.*** Verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed.

The licensee conducts area radiation surveys in accordance with Reg Guide 10.8 (Rev. 2). Weekly smears are usually performed on Friday each week, with the results reviewed quarterly by the consultant and RSO. The smears are counted using the licensee's Ludlum 2200 counting system. Trigger levels are set at 2000 dpm for contamination surveys and for area surveys, readings above .1 mR/h.

The inspector determined through interview of the NMT and a random review of the survey and smear records between March and June 2001 indicated that no contamination levels had exceeded the trigger levels or limits allowed for members of the public as specified in 10 CFR 20.

The licensee possesses Cs-137 and Co-57 check/reference sources and inventories are performed daily when a constancy test is performed. Leak tests were performed prior to receipt from the vendor and are due in August 2001.

The licensee is required to follow Appendix I for safe use of radiopharmaceuticals which was observed by the inspector that the NMT was meeting the requirements.

Within the areas inspected, no violations of NRC requirements were identified.

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)

✓ ***General Training***. Verify that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations.

✓ Verify that authorized users and workers understand the mechanism for raising safety concerns.

N/A Randomly examine records of training and periodic retraining of personnel and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required.

✓ ***Operating and Emergency Procedures***. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures.

✓ Examine the licensee's emergency procedures, to determine that these procedures are as approved by NRC.

N/A Examine revised procedures. Through discussions with workers, verify that licensee personnel understand and implement the established operational and emergency procedures and are aware of procedural revisions.

N/A ***Radiopharmaceutical Therapy Training***. Verify that the licensee provides radiation safety instruction for all personnel caring for patients receiving radiopharmaceutical therapy, in accordance with 10 CFR 35.310.

The inspector determined through interview of the NMT that initial training was provided by the consultant and local nuclear pharmacy staff prior to patient studies being initiated.

Within the areas inspected, no violations of NRC requirements were identified.

10. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release)

✓ ***Radiation Protection Program*** Verify that the licensee has developed and implemented a written radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the

program is reviewed at least annually, both for content and implementation.

✓ ***Radiation Protection Procedures.*** Verify that changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements. Determine whether the licensee was required by 10 CFR 35.13 to apply for license amendments for any of these changes.

✓ ***Personnel Dosimeters.*** Verify that personal dosimetry devices are worn by appropriate licensee personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved and accredited processor.

N/A ***Exposure Records.*** Verify that, pursuant to 10 CFR 20.2106, the licensee maintains records of doses received by all individuals for whom monitoring is required.

N/A ***Patient Release.*** Determine by observing, and discussing with the licensee, that a process exists to establish that a patient administered radioactive material is releasable from control under 10 CFR 35.75. Determine that written instructions are provided to released individuals on actions recommended to maintain doses ALARA, if doses to other individuals are likely to exceed 1 mSv (100 mrem). Verify that the licensee is recording: (a) the basis for release of patients, when necessary; and (b) that instructions are provided to breast-feeding women when required.

The licensee's radiation protection program involves external dose monitoring that includes both whole body and extremity dosimeters provided by an approved NVLAP dosimetry vendor. No dosimetry reports have been received.

Within the areas inspected, no violations of NRC requirements were identified.

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)

✓ ***Waste Storage and Disposal.*** Verify that written procedures for waste storage and disposal have been established in a manner approved by management and are readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities. Verify that the waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of 10 CFR 20.1301, "Dose limits for individual members of the public." Verify that disposal of decay-in-storage waste is performed in accordance with 10 CFR 35.92 and license conditions. Verify that the licensee is conducting appropriate surveys and defacing radioactive material labels before disposing of the waste.

✓ Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

N/A Review the licensee's procedures and records to verify that each shipment of radioactive waste intended for offsite disposal is accompanied by a shipment manifest that includes all the information required by Section I of Appendix F to Part 20.

N/A Review the licensee's procedures and records to verify that each package of radioactive waste intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix F to 10 CFR 20].

N/A Verify, through review of records and procedures, that releases into a public sanitary sewerage system, if any, are consistent with the form and quantity restrictions of 10 CFR 20.2003. Pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water.

N/A Effluents. Verify that effluent releases to sanitary sewerage and septic tanks are according to 10 CFR 20.2003 and 20.1003, respectively, and that treatment or disposal of waste by incineration is according to 10 CFR 20.2004.

✓ Review the licensee's ALARA goals, and determine if they are sufficiently challenging yet realistic. Determine if the licensee understands and implements these goals. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

N/A Review and verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within the limits established by the license and other regulatory requirements and are ALARA.

N/A Randomly select procedures for both liquid and airborne systems and determine the quality of the relevant procedures, determine the degree to which ALARA techniques are incorporated into them, and verify that the licensee's procedures are being followed. Determine the extent to which process and engineering controls are used to minimize effluents.

N/A Determine whether effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturer's recommendations and good health physics practices.

N/A Determine if all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

N/A Additional inspection requirements are specified in Inspection Procedure (IP) 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

✓ ***Transfer.*** Verify that wastes are transferred to an authorized recipient specifically licensed to receive radioactive waste.

✓ ***Records.*** Review the records of waste storage, transfer, and disposal to verify that disposals are made in accordance with the requirements of Part 20 and the license, and that the records are complete and accurate for each type of disposal.

The inspector determined through interview of the NMT that the majority of waste is returned to the nuclear pharmacy. Other waste is stored for decay. No disposal of decay-in-storage waste to date of the inspection.

Within the areas inspected, no violations of NRC requirements were identified.

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

N/A ***Financial Assurance and Decommissioning.*** Review the licensee's records of information important to the safe and effective decommissioning of the facility. Verify that the records are complete, updated, and assembled appropriately, in accordance with the requirements in 10 CFR 30.35(g). Review the licensee's list of restricted areas required under 10 CFR 30.35(g)(3) and determine whether laboratories or other rooms have been released since the last inspection. If areas have been released, verify that the licensee has adequately decontaminated each room and documented the basis for releasing each room. Perform confirmatory measurements to verify that radiation and contamination levels are below release limits. Document the location of the released rooms in the inspection record, and document your findings regarding the adequacy of the licensee's decontamination.

N/A Through observations, discussions with licensee personnel, and records review, verify whether radiological conditions at the facility have changed since the financial assurance instrument and/or decommissioning plan was submitted such that either document needs to be changed to address the new radiological conditions. If changes that may affect the financial assurance instrument or decommissioning plan are identified, immediately contact regional management from the licensee's site, to discuss the situation.

N/A If a parent company guarantee or a self-guarantee is used to ensure decommissioning financial assurance, review the licensee's financial assurance file to ensure that 10 CFR Part 30, Appendix A or Appendix C requirements are met.

✓ ***Decommissioning Timeliness.*** On all inspections, review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). [Note: *In accordance with Chapter 8, Section 8.6.10 a., page 40, of the enforcement manual, Licensees are* ***not*** *required to notify NRC when a decision is made to permanently cease principal activities in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements. Also,*

*Licensees are **not** required to notify NRC when no principal activities have been conducted for a period of 24 months in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.*]

The licensee is not required to post financial assurance for decommissioning, however, the licensee maintains records for future decommissioning purposes. Principal activities are ongoing.

Within the areas inspected, no violations of NRC requirements were identified.

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)

__✓__ ***Transportation.*** Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and DOT regulations for transportation of radioactive materials.

Package opening procedures include surveys of the package and an exterior and unit dose wipe test well within the 3 hour time period requirement. Packages are wipe tested and surveyed prior to pick up by the vendor.

Within the areas inspected, no violations of NRC requirements were identified.

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; over exposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals.)

__✓__ ***Notifications and Reports.*** Determine compliance with the regulations and license requirements for notification and reports to NRC and individuals. Verify that the licensee is in compliance with the requirements in 10 CFR 35.14, for medical licensees, to notify the Commission about changes in the authorized user, authorized nuclear pharmacist, or RSO.

__N/A__ Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually.

The inspector determined through interview of one NMT, review of consultant reports and RSC meeting minutes, that the licensee has not experienced any spills, fires, explosions, fatalities, package contamination exceeding regulatory limits, or other lost/stolen/missing licensed material. The NMT has documented one minor contamination event.

The licensee is not required to provide a Part 19 report of annual exposure.

Within the areas inspected, no violations of NRC requirements were identified.

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material.)

__✓__ ***Posting and Labeling***. Verify that the licensee has posted the appropriate license documents, regulations, notices, procedures, and forms. Examine locations where notices to workers are posted. Determine whether proper caution signs are posted at access points to areas containing radioactive materials, radiation areas, and areas containing airborne radioactive materials. Verify that containers of licensed material are labeled appropriately.

The inspector observed the postings required by Part 19 on a wall in the scanning area. A "Caution Radioactive Materials" sign was posted on the scanning room door.

Waste containers, vials, and syringes containing radiopharmaceuticals were properly labeled.

Within the areas inspected, no violations of NRC requirements were identified.

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

__✓__ ***Independent and Confirmatory Measurements***. Conduct independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Compare and verify, on a sampling basis, survey results or data that are used by the licensee to show compliance with the regulations or license conditions. Conduct independent measurements to ascertain the radiological conditions of the facility. Conduct these independent measurements on all inspections under this IP, unless warranted by special circumstances. If independent measurements were not made, provide a justification in the inspection record explaining why independent measurements were not performed. The inspector shall use radiation detection instruments that are calibrated, at a minimum, on an annual basis.

Survey Meter: **Ram Gam 1**
NRC Tag No. 056939
Calibrated 4/30/01

Using the check source affixed to the licensee's Ludlum 14C, a side-by-side comparison of the licensee's survey meter with the inspector's revealed that the licensee's responded comparatively. The licensee's check source reading was accurately labeled on the side of the meter.

Surveys in the scanning areas indicated only background readings of less than .1 mR/h. Surveys of the hot lab area did not reveal any readings greater than .2 mR/hr

where the NMT works while preparing doses. Survey results were consistent with the licensee's.

Within the areas inspected, no violations of NRC requirements were identified.

17. VIOLATIONS, NON-CITED VIOLATIONS 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.)

No violations of NRC requirements were identified during the course of the inspection. During the exit meeting a clear NRC 591 form was issued to the licensee staff.

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

***Tim Johnson, COO**
#*Greg Elliott, Director of Radiology
***Richard Reber, MD, RSO, authorized user (AU)**
#*Charlotte Thurman,Nuclear Medicine Technologist

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight	( ) Y (✓) N
B.	RSO too busy with other assignments	( ) Y (✓) N
C.	Insufficient staffing	( ) Y (✓) N
D.	RSC fails to meet or functions inadequately	( ) N/A ( ) Y (✓) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A ( ) Y (✓) N

Remarks (consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program):

None.

PART III - POST INSPECTION ACTIVITIES

1. REGIONAL FOLLOW-UP ON PEFs:

   No negative PEFs were identified.

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

   A debriefing with the Division Management concerning this inspection will be conducted on 7/18/2001.

END