18 DEC 1981

Docket No. 30-1786

MEMORANDUM FOR: James H. Joyner, Chief, Technical Inspection Branch

FROM: John D. Kinneman, Chief, Materials Radiological Protection Section

SUBJECT: SELECTION OF APPROPRIATE ENFORCEMENT ACTION FOR THE NATIONAL INSTITUTES OF HEALTH (LICENSE NO. 19-00296-10)

An inspection at the National Institutes of Health on January 5-8, 1981 identified two items of noncompliance, including one which is classified as a Severity Level III violation according to the Interim Enforcement Policy. We have reviewed the case to determine whether escalated enforcement is appropriate and have determined that such action is not appropriate in this case.

The apparent Severity Level III violation is for inadequate security of licensed material. Even though areas containing licensed material were unlocked and not under constant surveillance when licensed material was stored there, it is the inspector's opinion, under the particular circumstances, that access by unauthorized personnel was unlikely. The amounts of material not secured were small and did not present an attractive target for removal. The other violation was of Severity Level IV.

While there are concerns regarding management controls in specific areas of the licensee's radiation protection program expressed in the attached letter, the NIH has made a substantial commitment to radiation safety. The NIH has an extremely large program using licensed material which is well administered. Their response to these concerns will represent fine-tuning of important elements of the program.

I recommend that the attached letter be sent to the licensee. In accordance with EGM-81-08, the proposed letter informs the licensee of our consideration and rejection of civil penalties.

Original Signed By:
John D. Kinneman, Chief
Materials Radiological Protection Section

Attachment: As Stated

RIII:MRPS	RIII:MRPS
Nicolosi/mjd	Kinneman
11/16/81	11/16/81

OFFICIAL RECORD COPY

Docket Nos. 30-01786
30-07724
30-06922
30-08478
30-17777
30-17787
70-1366

18 DEC 1981

Department of Health and Human Services
National Institutes of Health
ATTN: Thomas E. Malone
Acting Director
Bethesda, Maryland 20014

Gentlemen:

Subject: Inspection 81-01

This refers to the routine inspection conducted by Dr. J. Glenn, Mr. J. Nicolosi, Mr. C. Rowe and Ms. J. McGinness of this office on January 5 - 8, 1981 of activities authorized by NRC License Nos. 19-00296-10, 19-00296-11, 19-00296-12, 19-00296-17, 19-00296-18, 19-00296-19, and SNM-1345, and to the discussions of our findings held by Dr. Glenn with Dr. Goldberger and other members of your staff at the conclusion of the inspection.

Areas examined during this inspection are described in the Office of Inspection and Enforcement Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspectors, and observations by the inspectors.

Our inspectors also verified the steps you have taken to correct the items of noncompliance brought to your attention in the enclosure to our letter following the previous inspection. We have no further questions regarding your action at this time.

In addition, our inspectors examined those activities conducted under your licenses relating to the subject covered in your letter to this office dated September 11, 1979. We have no further questions regarding this matter.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These

RI:DETI	R1:DETI	R1:DETI	R1:E&I	R1:DETI
Nicolosi/wb	Glenn	Kinneman	Carlson	T. Martin
12/3/81	12/3/81			

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items of noncompliance have been categorized into the levels described in the Federal Register Notice (45 FR 66754) dated October 7, 1980. You are required to respond to this letter and in responding should follow the instructions in Appendix A.

Item A in the attached Notice of Violation is classified as a Severity Level III violation in accordance with the Interim Enforcement Policy described in the Federal Register Notice referenced above. As stated in Section IV.B of the Policy, monetary civil penalties are normally assessed for Severity Level III Violations. After careful consideration of this specific violation, including the fact that the amounts of licensed material unsecured were small, we have determined that civil penalties are not appropriate. Similar violations of this type in the future may result in imposition of civil penalties.

During discussions at the conclusion of the inspection, Dr. Glenn expressed our concern regarding the apparent weakness of your management control systems in several specific areas. The first area of concern is management review of audits and prompt implementation of corrective actions. In this regard, the inspection identified two instances of deviations from previous written commitments to the NRC. Your letter dated April 13, 1979 stated that results of laboratory inspections would be communicated to a specified level of NIH management for action to secure compliance. Your letter dated September 24, 1979 stated that results of audits of waste disposal activities would be recorded. From the results of this inspection it appears these commitments were not implemented. We believe that accurate recording of audit/inspection results and careful review of such results by responsible licensee management are essential to the maintenance of a strong, effective radiation protection program. The second area of concern regards communication between the Radiation Safety Staff and the laboratories with respect to assignments and terminations of radiation workers. Such communication is important to proper implementation of your training, dosimetry and other radiation protection programs. In your reply to this letter, please discuss your deviations from these commitments and describe those actions taken or planned to improve communication between the Radiation Safety Staff and laboratories and to improve your management control systems in these areas.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room. If this report contains any information that you (or your contractors) believe to be exempt from disclosure under 10 CFR 9.5(a)(4), it is necessary that you (a) notify this office by telephone within ten (10) days from the date of this letter of your intention to file a request for withholding; and (b) submit within 25 days from the date of this letter a written application to this office to withhold such information. Consistent with section 2.790(b)(1), any such application must be accompanied by an affidavit executed by the owner of the information which identifies the document or part sought to be withheld, and which contains a full statement of the reasons on the basis which it is claimed that the information should be withheld from public disclosure. This section further requires the statement

to address with specificity the considerations listed in 10 CFR 2.790(b)(4). The information sought to be withheld shall be incorporated as far as possible into a separate part of the affidavit. If we do not hear from you in this regard within the specified periods noted above, the report will be placed in the Public Document Room. The telephone notification of your intent to request withholding, or any request for an extension of the 10 day period which you believe necessary, should be made to the Supervisor, Files, Mail and Records, USNRC Region I, at (215) 337-5223.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning this inspection, we will pleased to discuss them with you.

Sincerely,

Original Signed By:

Thomas T. Martin, Director,
Division of Engineering and
Technical Inspection

Enclosures:
1. Appendix A, Notice of Violation
2. Combined Office of Inspection and Enforcement Inspection Report Numbers 30-01786/81-01, 30-07724/81-01, 30-06922/81-01, 30-08478/81-01, 30-17777/81-01, 30-17787/81-01, and 70-1366/81-01

cc w/encls:
R. Broseus, Chief, Radiation Safety Branch ✓
Public Document Room (PDR)
Nuclear Safety Information (NSIC)
State of Maryland (2) ✓

bcc w/encls:
Region I Docket Room (with concurrences)
Chief, Operational Support Section (w/o encls) ✓

APPENDIX A

NOTICE OF VIOLATION

Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20014

Docket No. 30-1786
License No. 19-00296-10

As a result of the inspection conducted on January 5-8, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee.

Contrary to this requirement, on January 7, 1981, approximately 90 microcuries of iodine-125 were stored in an unlocked refrigerator in a hallway of Building 10 on the 12th floor in Location 12 - Elevator 9, and a trash container labeled as radicactive waste was stored in a hallway on the 11th floor of building 10 outside of Room 12N208. These radioactive materials were neither under the constant surveillance nor the immediate control of the authorized user and were accessable to unauthorized individuals.

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

B. Condition 25 of License No. 19-00296-10 requires that you possess and use licensed materials in accordance with statements, representations, and procedures contained in certain referenced applications and letters. Included is an application dated March 3, 1973 which includes your document entitled: "The National Institutes of Health Radiation Safety Guide."

Item 4.e (page 5) of the "Radiation Safety Guide" requires that users use pipette filling devices and never pipette by mouth.

Contrary to this requirement, on January 7, 1981, a mouth pipetting device was observed in Room 11D07, which is restricted for the purposes of radiation protection. Individuals frequenting this restricted area stated that mouth pipetting had occurred in the laboratory where radioactive materials are used.

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

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Pursuant to the provisions of 10 CFR 20.201, the National Institutes of Health is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation. Where good cause is shown, consideration will be given to extending your response time.

Date 18 DEC 1981

Thomas T. Martin

Thomas T. Martin, Director,
Division of Engineering and Technical
Inspection

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

Region I

Report Nos. 030-01786/81-01, 030-07724/81-01, 030-06922/81-01, 030-08478/81-01, 030-17777/81-01, 030-17787/81-01, 070-01366/81-01

Docket Nos. 030-01786, 030-07724, 030-06922, 030-08478, 030-17777 030-17787, and 070-01366

License Nos. 19-00296-10, 19-00296-12, 19-00296-18, SNM-1345 19-00296-11, 19-00296-17, 19-00296-19

Category G-1 Priority III

Licensee: Department of Health and Human Services

National Institutes of Health

Bethesda, Maryland 20014

Facility Name: National Institutes of Health

Inspection at: Bethesda, Maryland

Inspection conducted: January 5-8, 1981

Inspectors: John Glenn — John Glenn, Radiation Specialist — 10/30/81 date signed

John Glenn — Joy McGinness, Radiation Specialist — 11/3/81 date signed

James F. Nicolosi — James Nicolosi, Radiation Specialist — 11/3/81 date signed

Claude Rowe — Claude Rowe, Radiation Specialist — 10/30/81 date signed

Approved by: John D. Kinneman — John D. Kinneman, Chief, Materials Radiological Protection Section — 11/3/81 date signed

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Inspection Summary:
Inspection on January 5-8, 1981 (Combined Report Nos. 30-01786/81-01, 30-07724/81-01, 30-06922/81-01, 30-08478/81-01 30-17777/81-01, 30-17787/81-01 and 70-01366/81-01)
Areas Inspected: Routine, announced inspection including a review of licensee action on previous inspection findings, organization, internal audits, training, radiation protection procedures, receipt and transfer of licensed material, personnel exposure monitoring, radioactive effluents and waste disposal, emergency planning, licensee event report, posting, labeling and control, and confirmatory measurements.
Results: Of the 12 areas inspected, two apparent items of noncompliance were identified in two areas (Violation - mouth pippetting of solutions in a restricted area, Paragraph 6.e; Violation - Failure to adequately secure licensed material to unauthorized individuals, Paragraph 12). In addition, two deviations from written commitments were identified (Failure to communicate audit results to required level of management, Paragraph 4; Failure to maintain records of audits, Paragraph 7).

DETAILS

1. Persons Contacted

* Dr. R. Goldberger, Deputy Director, NIH
* Dr. G. Johnston, Chairman, Radiation Safety Committee
* Mr. R. Broseus, Radiation Safety Officer and Chief, Radiation Safety Branch
  Dr. W. E. Barkley, Director, Division of Safety Staff
* Mr. R. Zoon, Chief, Health Physics Section, Radiation Safety Branch
  Mr. J. Austin, Chief, Radiation Support Section

In addition the inspectors interviewed five health physicists, three health physics technicians, two contractor employees, nine research investigators, and five individuals in the nuclear medicine program.

*denotes those attending the exit interview.

2. Licensee Action on Previous Inspection Findings

(Closed) Noncompliance (30-1786/79-01): Failure to instruct employees working in restricted areas.

Based on interviews with employees and a review of training records it was determined that the licensee has increased the frequency of training. No individual was identified working with radioactive materials who had not received required training.

(Closed) Noncompliance (30-1786/79-01): Failure to provide appropriate dosimetry to individuals working with radioactive materials.

Based on observations of laboratory practices and a review of licensee records, the inspectors determined that the licensee evaluates exposure to individuals and assigns appropriate dosimetry to measure exposure.

(Closed) Noncompliance (30-1786/79-01): Failure to evaluate discharges of radioactive waste to the sanitary sewer system.

Based on a review of records of laboratory surveys, the inspectors determined that all significant quantities of radioactive materials discharged to the sanitary sewer system are evaluated and controlled.

(Closed) Noncompliance (30-1786/79-01): Failure to limit radiation levels in unrestricted areas.

Based on records of licensee surveys and confirmatory measurements by the inspectors, it was determined that radiation levels in unrestricted areas are evaluated and maintained within NRC limits.

(Closed) Noncompliance (30-1786/79-01): Failure to wear protective clothing.

Based on records of laboratory surveys and the inspectors observation of laboratory practices, the inspectors determined that the licensee identifies and requires corrective action when individuals fail to wear protective clothing.

(Closed) Noncompliance (30-1786/79-01): Failure to prevent smoking in restricted areas.

Based on records of laboratory surveys and the inspector's observations of laboratory practices, the inspectors determined that the licensee identifies infractions of this rule and requires corrective actions.

(Closed) Noncompliance (30-1786/79-01): Failure to perform daily surveys in restricted areas.

Based on statements by licensee representatives and a review of records, the inspectors determined that daily surveys are required and corrective actions are taken when infractions are identified.

(Closed) Noncompliance (30-1786/79-01): Failure to post rooms where radioactive materials are used and stored and failure to label refrigerators containing radioactive materials.

From inspector observation and a review of licensee laboratory surveys, it was determined that posting and labeling are required by the licensee and deficiencies are corrected when identified.

3. Organization

The National Institutes of Health (NIH) is an agency within the Public Health Service of the Department of Health and Human Services. Within NIH the organization consists of independent Institutes, Bureaus, and Divisions all reporting to the Director of NIH.

The Radiation Safety Branch is located within the Division of Safety Staff, Office of Research Services. The Radiation Safety Branch has two sections. The Health Physics Section is responsible for monitoring of activities, training, calibrations, record keeping, performing leak tests, emergency planning, and risk assessment. The Radiation Support Section receives, delivers, and ships all radioactive materials; supervises and coordinates radioactive waste disposal; operates and maintains laboratory support services in the Building 21 Isotope Laboratory; and maintains an inventory of all radioactive materials at NIH. The Radiation Safety Committee has the authority and responsibility to review and approve uses of licensed materials under the NIH byproduct materials licenses and to withdraw such authorization if NIH rules and procedures are not followed.

A review of minutes of the Radiation Safety Committee showed that required meetings had been held each calendar quarter. Since the last inspection, meetings had been held March 1, 1979, April 25, 1979, August 1, 1979, October 24, 1979, January 23, 1980, April 30, 1980, July 7, 1980, and October 10, 1980. Records showed that the committee had reviewed proposed human studies, authorized new users of byproduct material, and had temporarily withdrawn authorization to use byproduct material in one instance where infractions of required procedures had been noted. When corrective actions were implemented, authorization to use byproduct material was reinstated.

No items of noncompliance were identified.

4. Licensee Internal Audits

To aid in monitoring compliance in individual laboratories, NIH has contracted with Radiation Management Corporation to perform periodic surveys in laboratories. Radiation Safety staff representatives stated that approximately 5,000 laboratory surveys are performed annually by the contractor and that infractions are identified in 20-25 percent of these surveys. In addition, the Radiation Safety staff performs approximately 1,000 laboratory surveys per year. The inspectors noted that the majority of staff survey records reviewed indicated the surveys were conducted in response to positive film badge readings, bioassay survey results, or contractor survey results. The contractor's surveys cover compliance with the licensee's procedures as well as measurements of radiation and contamination levels in the laboratories.

Radiation Safety staff representatives stated that any positive finding of individual exposure or any identified infraction was reviewed by a member of the Radiation Safety Branch. A review of representative records by the inspectors demonstrated that in each such instance where an exposure or infraction had been identified, an evaluation and communication with the individual user had been made. In many instances, the communication was by telephone and no further evaluation was found necessary by the staff.

An inspector accompanied the licensee's contractor (Radiation Management Corporation) while the contractor was surveying and auditing these labs for compliance with the licensee's requirements for safe use of licensed material.

The inspectors reviewed a random sample of 125 contractor surveys of laboratories. The sample was chosen from those for which infractions had been identified. The following infractions had been identified in this sample:

1. Contamination in excess of 100 dpm/100 cm^2 - 88
2. Smoking, eating, or drinking in laboratories - 9
3. Improper waste storage - 8
4. Failure to cover surfaces with absorbent paper - 6

5.	Lab workers not instructed	- 5
6.	Gloves or labcoats not worn	- 4
7.	Pippeting by mouth	- 3
8.	No records of lab surveys	- 3
9.	Posting deficiencies	- 3

Each record reviewed had been evaluated by a member of the Radiation Safety Branch as indicated by written comments at the bottom of the sheet and corrective action taken.

The inspectors interviewed Radiation Safety Branch staff, Division of Safety staff representatives, and NIH management regarding the enforcement of compliance at NIH. Most comments mentioned the high regard for the Radiation Safety staff as safety professionals offering a service to the research staff. NIH management representatives stated that they wished to preserve the present role of the Radiation Safety Branch. They stated that NIH management took the responsibility for enforcement when violations were identified and that the Radiation Safety Branch staff's role was one of guidance rather than enforcement.

Radiation Safety Branch representatives stated that only serious infractions or instances where the staff believes voluntary compliance cannot be achieved are brought to the attention of the Radiation Safety Committee and NIH management. The inspectors noted that this procedure differed from the statement made in the NIH letter to the Region I office dated April 13, 1979 which stated:

> "5. The Radiation Safety Branch will provide the NIH Deputy Director for Science with a list of laboratories inspected and violations found each month. Copies will be sent to the Radiation Committee and each of the Scientific Directors for action in securing compliance."

This represents a deviation from a previous commitment.

5. Training

Individuals must complete a two week course given by the Radiation Safety Branch before being designated by the Radiation Safety Committee as an authorized user. Authorized users must approve all purchase requests and are responsible for the activities of individuals using radioactive materials under their supervision.

Authorized users have the primary responsibility for instruction of individual users working under their supervision. In addition, the Radiation Safety Branch offers a one day course for individual users. A representative of the Radiation Safety Branch stated that at the time of the inspection in February 1979, approximately 500 individual users had not taken the one day course. As of January 1981, the representative stated that no more than 50 individuals in contact with radioactive materials had not attended the one day course. Records reviewed and interviews of NIH employees by NRC inspectors showed that individual users, nursing staff, and maintenance employees had received instruction in radiation safety procedures.

Licensee representatives stated that requests for training and dosimetry monitoring for new employees are initiated by individual authorized users. The licensee identifies some individuals requiring training or monitoring by contractor or licensee laboratory survey visits. Representatives stated that there was no established method for notifying the Radiation Safety Branch of new assignments or terminations other than notification by the authorized users. Licensee representatives stated that in a few instances, laboratories had been abandoned by departing authorized users without notification of the Radiation Safety Branch.

No items of noncompliance were identified.

6. Radiation Protection Procedures

a. Irradiators:

The inspectors reviewed the inventory of sealed source irradiators and toured the facilities in which the irradiators were located. The licensee has eight Category I (self-contained) irradiators which are key operated. The inspectors noted from observations during the tour and discussions with authorized users that each authorized irradiator user maintains a user log, list of qualified operators, procedures for normal and emergency operation, and maintains security control over the keys for operation of the irradiators to assure only authorized operators have access to the key. Facilities, equipment and training of authorized users and operators were observed to be as authorized by license conditions. Irradiator interlocks were functional and independent measurements of radiation levels during operation of the irradiators were in agreement with the licensee's results. The inspector noted that all rooms containing irradiators were properly posted and secured. Additionally, the inspector observed the installation of a recently purchased irradiator in Building 37 by J. L. Shepherd, a California based irradiator manufacturer. The inspectors reviewed the leak test results for all irradiator sources for the previous two years and noted that they were tested at six month intervals and all leak test results were less than 0.005 uCi.

No items of noncompliance were identified.

b. Sealed Source Inventory:

The inspectors reviewed the licensee's records of sealed source inventory and leak test results. The licensee performs a sealed source inventory semi-annually and leak tests are performed by RMC contractor personnel semi-annually. The inspector noted that two sources, Tc-99 and Sr-90 totalling approximately 20 uCi, were unaccounted for on the July 1980 inventory. A licensee representative supplied documentation of their search for the sources and calculations made to determine that the sources presented no significant hazard to personnel. The inspector noted that seven sources were

unaccounted for by RMC personnel during their performance of semi-annual leak test in January 1981. The licensee's representative stated that they were in the process of resolving this discrepancy. The inspectors randomly selected several sources from the inventory list and verified by hands-on inventory that they were in the location specified on the inventory list.

The licensee notified the inspectors by letter dated January 12, 1981 that all sources were accounted for.

No items of noncompliance were identified.

c. Nuclear Medicine - Imaging

The inspectors made a tour of the nuclear medicine facility located in Building 10. The inspectors noted that the restricted areas were appropriately posted and contained information on procedures to follow in case of emergencies. The facilities were as described in the license application. Personnel in the department were observed by the inspectors to be wearing the appropriate whole body and extremity monitoring devices.

The inspectors reviewed the protocol for ordering diagnostic tests and therapeutic procedures for patient evaluation and treatment. The licensee has had no reportable mis-administrations as defined under 10 CFR 35.33. All nuclear medicine patient procedures currently being performed have been authorized by the licensee's radiation safety committee.

The inspectors interviewed the nuclear pharmacist with respect to radiation safety procedures while preparing radiopharmaceuticals. The radiopharmacist stated that he used vinyl gloves and syringe shields in all dose dispensing procedures and that he monitored his hands at least twice daily for contamination, once before lunch and once before leaving for the day. A review of records indicated that he surveyed dose preparation and injection areas on a daily basis for surface contamination. The inspectors evaluated the licensee's instrumentation used for personnel monitoring and found it to be adequate for the purpose intended.

The radiation levels in unrestricted areas around the Nuclear Medicine Department were found by the inspectors to be within regulatory limits. Security of licensed materials was found to be adequate.

No items of noncompliance were identified.

d. Central Pharmacy

The inspectors reviewed the daily operation in the central radio-pharmacy located in Building 21. All radioactive materials used for human use are dispensed from this point along with those for research in vivo studies.

There are three radiopharmacists on staff. One is rotated weekly to the central dispensing area in the Nuclear Medicine Department. The remaining two radiopharmacists carry on the dispensing of radiopharmaceuticals to the remainder of NIH. All three pharmacists have completed NIH's two week radiation safety course and have worked here for several years.

The inspectors toured the radiopharmacy which is divided into three main areas; quality control, elution and preparation, and a third area for work with volatile radioactive materials.

Multi-dose vials are shielded with color coded lead pigs and transported in a lead carrier by the radiopharmacist to Building 10 where the Nuclear Medicine Department is located.

The radiopharmacist was observed by the inspectors to be wearing the proper whole body and hand dosimetry and gloves while performing various procedures within the radiopharmacy.

All work with volatile radioactive materials is done in an enclosed work area within a hood which is supplied with the appropriate filter systems and air monitoring of the breathing zone and release to unrestricted area. (Effluent releases to unrestricted and restricted areas are discussed in Section 9). The inspectors made an independent survey of the air flow rates in two hoods used in the radiopharmacy with the licensee's thermal anemometer. Dry wipes were taken in the hood where iodine work is performed. Results of these wipes are found in the independent survey section.

Pharmacists are required to have a whole body count on a monthly basis, but most have them done weekly. In addition, monthly evaluations are performed to determine if thyroid uptakes have occurred.

Review of the radioactive waste disposal from the pharmacy showed that long-lived materials are being separated from short-lived materials. One of the two molydenum-99/technetium-99m generators is returned for decay, the second is sent to the nuclear medicine department to be used as a backup source of technetium-99m for emergency scans during non-regular working hours.

No items of noncompliance were identified.

e. Therapy

The inspectors reviewed the safety procedures involved in the licensee's brachytherapy program. Information was obtained through interviews with the health physicist assigned to the brachytherapy program. Presently the licensee's use of licensed material is limited to

experimental use of iridium-192 seeds for surgical implants. A record review indicated ten surgical implantations of iridium 192 during 1980. All shipments are verified and assayed for total activity by the health physicist upon receipt and prior to surgical implant. The licensee provides whole body monitoring for all individuals involved in these therapeutic procedures. The licensee also employs the use of portable shields around the patient's bed to insure compliance with 10 CFR 20.105. A review of survey records in the areas surrounding the patient's room verified compliance for radiation levels in unrestricted areas. Additionally, survey records also indicated compliance with 10 CFR 35.14(5)(b)(vii). The inspectors determined that the licensee obtained the iridium-192 sources from an authorized distributor and satisfied the requirements of 10 CFR 71.5 in returning used sources to the manufacturer.

No items of noncompliance were identified.

f. Laboratories - Direct Observation

The inspectors reviewed the licensee's procedures for working with unsealed volatile forms of licensed material, including observation of an iodination procedure using four millicuries of iodine-125. The inspectors interviewed the investigators prior to the procedure. The investigators had attended the one day training course prior to working under the authorized user and had performed three prior iodinations. The inspectors observed that the investigators were wearing the required monitoring and protective clothing. The iodination was performed in a hood box employing charcoal filtration of effluent located in a larger lab hood which a licensee representative stated contained a bank of charcoal filters located just prior to the release of gaseous effluent to unrestricted areas.

Licensee representatives stated that instruments and equipment used during such procedures involving licensed material are monitored for contamination prior to letting the investigators remove them for use in their individual labs. The inspectors also noted a survey meter located at the entrance to this lab which is used to monitor hands, feet and clothing of investigators as they leave this area. The inspectors observed that a supervisor required an investigator to remove one glove that had become contaminated during the procedure so as to minimize the spread of contamination. The inspectors also noted that a continuous breathing zone monitor was functional during the procedure. In an independent measurement the inspectors checked the lab hoods and hood boxes to evaluate air flow and negative pressure of the lab. The inspectors used a calibrated thermal anemometer supplied by the licensee to make this assessment. All lab hood and hood boxes were found to have adequate exhaust rates.

An inspector reviewed corrective action for incidents of mouth pipetting in two restricted areas which were identified during routine licensee audits in Building 10. The inspector observed the notification of violation from the Radiation Safety Branch had been posted in Lab 12N250 and had been initialed by all radiation personnel who worked in this area. Lab 11D07 was posted as a restricted area. A list of safety procedures to be followed was posted in this lab. The inspector observed a mouth pipetting apparatus sitting in a beaker containing solution. Upon questioning by the inspector, the investigator stated that material was routinely mouth pipetted in this restricted area. The investigator had made no evaluation to insure that the equipment employed in the mouth pipetting was free of contamination from licensed material.

Item 4.c (page 5) of the "Radiation Safety Guide" requires that users use pipette filling devices and never pipette by mouth. The finding that mouth pipetting had occurred in a restricted area represents noncompliance with Condition 25 of License No. 19-00296-10.

7. Receipt and Transfer of Licensed Material

a. Orders

Representatives of Radiation Safety Branch stated that all orders for radioisotopes must be entered on NIH Form 88-1 which is then submitted to the Radiation Safety office. The information from this form is entered into a computer to verify that the authorized user is authorized to receive the type and quantity of byproduct material, that proper dosimetry has been assigned to the listed users, and to assure that bioassay will be requested when the material is received, if required. All purchase orders require that radioactive materials be delivered to the Radiation Safety Office in Building 21. Radioactive shipments are opened and surveyed by members of the Radiation Safety Branch. The inspectors observed packages being inspected for damage, monitored for radiation levels and contamination, and wipes being taken of the inner vials. The inspectors observed that each purchase order number for a package was verified against a computer listing of approved NIH-88-1 forms. Licensee representatives stated that shipments are not transferred to users without a proper NIH-88-1 form.

No items of noncompliance were identified.

b. Waste

Packages of dry radioactive waste and liquid scintillation vials are prepared under the direct supervision of an assigned individual in the Radiation Safety Branch. Packaging of waste is performed by employees of a contractor, Radiation Service Organization, under the supervision of the assigned individual. Packaged waste is then transferred to the contractor as authorized by Maryland License No. MD-33-021-02. The assigned individual stated that quarterly audits of the waste contractor's activities are performed, but not documented.

This finding indicates a deviation from the commitment to maintain written documentation of these audits as stated in the licensee's September 24, 1979 response to IE Bulletin No. 79-19.

No packages on hand were ready for shipment; however, partially filled drums were opened and examined. These drums were clearly labeled and contained properly prepared waste. Licensee representatives stated that each package is surveyed for radiation levels and contamination, labeled, and sealed. Shipping papers reviewed showed each shipment includes papers showing the shipping name, radionuclide, transport group, form, activity, label category, transport index, and package type.

c. Transfer to Other Licensees

The inspectors reviewed documentation to verify that recipients were authorized to receive licensed materials shipped from NIH. For three of four shipments chosen, the licensee had on file a current copy of the recipient's license. In one instance, byproduct material had been shipped on the basis of an oral verification between a researcher at NIH and a researcher at the receiving institution. A representative of the Radiation Safety Branch stated that for future shipments verification by the Radiation Safety Branch would be required.

No items of noncompliance were identified.

8. Personnel Exposure Monitoring

a. External

The licensee's dosimetry records indicated that NIH provides film badge monitoring to nearly 4,000 individuals. Representatives stated that all individuals working with gamma emitters, X-ray producing machines, and penetrating beta emitters are required to wear a film badge dosimeter. In addition, film badges are issued to other workers if dosimetry is requested.

The inspectors reviewed computer generated summarys of exposure for 1979 and for 1980 through October. There were two apparent doses in excess of 1250 mrem in a quarter. One of these exposures was due to a coding error and was not an exposure received by the employee. Records of an investigation of a 1290 mrem exposure of an employee showed that the exposure was due to iodine-131 therapy the individual received as a patient.

A representative of the Radiation Safety Branch stated that any film badge exposure in excess of 100 mrem is investigated. The inspectors reviewed 23 reports of film badge investigations. The reports included an evaluation of the exposure, probable cause of the exposure, and proposed corrective actions. In addition, the investigator determined whether training had been given and whether extremity dosimetry was provided and worn. During 1979, seven individuals were noted who had not attended the one day training course at the time of the investigated exposure. Records indicated that during 1980 all of the individuals investigated had attended the training course. Twenty-one of twenty-three film badge exposures investigated involved users of phosphorus-32. Representatives of the Radiation Safety Branch stated that special attention has been directed toward reducing exposures to individuals using this isotope.

Summary exposure records show that only about 10 percent of badged employees received a measurable dose during 1978, 1979, and 1980. Only 1.5 percent of badged employees received a dose in excess of 100 mrem during the same period. The highest exposures were received by employees working with X-ray producing equipment. No individual working with radioisotopes was recorded to have received an annual occupational dose in excess of 700 mrem during this period.

No items of noncompliance were identified.

b. Internal

Personnel air sampling is required by the licensee whenever individuals work with volatile radioactive materials in excess of specified quantities. The inspectors reviewed records of personnel air samples for the two months previous to the inspection and found that all measured airborne concentrations were well below Appendix B, Table I, Column 1 levels when averaged over 40 hours continuous exposure. Representatives of the Radiation Safety Branch stated that no individuals had been exposed to airborne concentrations in excess of 10 CFR 20.103 limits since the last inspection.

Bioassays are required for individuals using volative radioactive materials in excess of the quantities specified in the September 10, 1973 letter referenced in License No. 19-00296-01. Records indicated that bioassays for persons performing iodinations are performed more frequently (monthly) and for smaller quantities (1 millicurie) than specified in this letter. Bioassay records showed that results are converted to whole body burdens and compared with action limits based on permissible body burdens listed in ICRP Publication 2. Bioassays are also performed at the request of individual users.

The inspectors reviewed a summary of bioassay results for 1979 and 1980. The highest body burdens recorded were 14.96 microcuries of tritium, 46 nanocuries of chromium-51, 73 nanocuries of iodine-125, 200 nanocuries of thallium-201, and 26.3 nanocuries of selenium-75. Records for each of the above exposures were reviewed and showed that evaluations had been made and corrective actions taken. Based upon these evaluations of exposure, no individual had been exposed to concentrations in excess of the limits in 10 CFR 20.103.

No items of noncompliance were identified.

9. Radioactive Effluents and Waste Disposal

Licensee representatives stated that all radioactive waste is disposed of by incineration, release to the sanitary sewer system, or transfer to a licensed waste disposal contractor.

Representatives of the Radiation Safety Branch stated that all radioactive materials for incineration are monitored and packaged for incineration under the supervision of their staff. Records showed that during 1979, 13.2 millicuries of carbon-14, 87.5 millicuries of tritium, and 9.5 millicuries of sulfur-35 were incinerated. During 1980, records showed that 6.1 millicuries of carbon-14, 109.0 millicuries of tritium and 7.5 millicuries of sulfur-35 were incinerated. The volume of air exhausted from the incinerator was recorded to be 4934 scfm. The incinerator was recorded to operate more than six hours per day for 260 days a year. Thus the licensee uses a dilution volume of 1.31×10^{13} cc/yr. Based on these measurements the licensee has calculated that average concentrations in effluent averaged over one year are less than ten percent of Appendix B, Table 2, Column 1 values. Records showed that ash samples are collected and determined to be below Appendix B, Table 2, Column 2 values in activity per gram before release.

Representatives stated that individual labs release only second rinsings of glassware to the sewer system. All other radioctive liquids are collected and monitored by the waste contractor under the supervision of the radiation safety staff. Containers of short lived isotopes or high concentrations are emptied into one of two 10,000 gallon holding tanks. Other containers are emptied directly into the sanitary sewer system. Records showed that each 10,000 gallon tank is emptied about once each year. Records were maintained of total releases to the sanitary sewer system. Records showed that during 1979, 2,343 millicuries of tritium, 105 millicuries of carbon-14, and less than 25 millicuries of other isotopes were released to the sanitary sewer system. Radioisotopes released during 1980 had not been summed, but the inspector observed that releases appeared to be less than in 1979. Condition 22 of License No. 19-00296-10 permits the release of 8,000 millicuries per year provided the concentration limits of 10 CFR 20.303 are met. Records showed that concentrations of radioactive material in sewage were less than one percent of the concentrations listed in Appendix B, Table I, Column 1 of Part 20.

Licensee representatives stated that concentrations of radionuclides are measured in effluent air from Building 21 and all hoods where iodinations are performed. Records were maintained showing a running twelve month average of airborne concentrations in effluent air. The highest concentrations were measured from Building 21 with iodine-125 the principal isotope. The samples are collected on charcoal for iodine and on silica-gel for tritium. The highest recorded concentration for a twelve month period was 0.33×10^{-11} microcuries per milliliter iodine-125, which is less than the value listed in Appendix B, Table 2, Column 2, of Part 20.

No items of noncompliance were identified.

10. Emergency Planning

A representative of the Division of Safety Staff stated that an informal emergency plan has been instituted and that a more formal plan is being developed. Call lists for various types of emergencies have been developed. Fire and police personnel have been briefed on the hazards at various locations at NIH. He also stated that the Clinical Center has a medical plan to be activated if five or more individuals are involved in a radiological incident. An agreement with another hospital has been made in case the Clinical Center is unable to accept incident victims.

No items of noncompliance were identified.

11. Licensee Event Report

By letter dated September 11, 1979 the licensee notified Region I that a waste storage tank had overflowed and released low concentrations of radioactive materials in water to an unrestricted area.

Records reviewed indicated only a small quantity of liquid was released (several gallons) and that a fraction was recovered. The contaminated area was flushed with large quantities of water. Based on the licensee's evaluation that iodine-125 concentrations did not exceed 6×10^{-4} microcuries per milliliter in tank waste, and the dilution obtained it appears that effluent water released from the restricted area did not exceed 2×10^{-7} microcuries per milliliter. Records of soil sample surveys indicate that maximum concentration in the immediate vicinity of the overflow were 4×10^{-7} microcuries of iodine-125 per gram.

Licensee representatives stated the overflow was due to a roof drain that unknowingly drained into the waste holding tank. They stated the roof drain has been disconnected from the waste tanks and that frequent checks of liquid levels are made. No alarms have been installed on the tanks and licensee representatives stated that their evaluation was that the corrective actions taken were adequate to prevent recurrence. The inspector noted that all additions to the tanks are made manually.

No items of noncompliance were identified.

12. Posting, Labeling and Control

The inspectors noted that all restricted areas visited during the inspection were appropriately posted. Areas where radioactive materials were stored were posted as required. Selected areas where materials were in storage were inspected to insure that all containers were labeled as to radionuclide, chemical form and activity and contained the standard label with the words "Caution - Radioactive Material". Waste containers examined were labeled as required.

The inspectors observed that at least 90 uCi of iodine-125 was stored in an unlocked refrigerator located in Building 10 on the 12th floor at location 12 - Elevator 9. A trash container labelled as radioactive waste was stored in the hallway on the 11th floor of Building 10 outside Room 12N208.

The finding that licensed materials were stored in unrestricted areas and were not under the constant surveillance nor the immediate control of the authorized user and were accessable to unauthorized individuals represents noncompliance with 10 CFR 20.207.

Licensee representatives stated that there is no system for accounting for licensed material used, stored and disposed of as waste. Licensee representatives acknowledged that the licensed materials could be directed to and from the licensee's facilities without any accountability from the authorized users. This matter will be further reviewed during a future inspection.

13. Confirmatory Measurements

Surveys by the inspectors in restricted and unrestricted areas through the licensee's facility showed that radiation levels complied with 10 CFR 20.101 and 20.105. In addition the inspectors took smears in Lab 12N252 in Building 10 and the central radiopharmacy and iodination labs in Building 21. These smears were analyzed in the Regional Office Laboratory located in King of Prussia, Pennsylvania. The inspectors' analysis confirmed the results obtained by the licensee during their contamination wipe test evaluations of these areas. The inspectors and the licensee obtained samples from two waste storage tanks. Analysis by Ge(Li) detector in the Regional Mobile Laboratory and by the licensee indicated some differences from the licensee's analysis.

These results were discussed in phone conversations with licensee representatives on February 12 and 13, 1981. The samples were taken on two different days rather than split and possibly taken from different depths in the storage tanks; therefore, it was decided to evaluate this matter further during the next inspection.

No items of noncompliance were identified.

14. Exit Interview

The inspectors met with Dr. Robert Goldberger, Deputy Director, and other individuals designated in paragraph 1, at the conclusion of the inspection on January 8, 1981. The inspectors summarized the scope and findings of the inspection.