34-00799-03
030-02658

VOID SHEET

TO: License Fee Management Branch

FROM: COLLEEN C. CASEY

SUBJECT: VOIDED APPLICATION

Control Number: 396362

Applicant: V.A. Cincinnati, OH.

Date Voided: 2/11/94

Reason for Void: The V.A. sent the wrong application with V.A. Cincinnati's cover letter. Actually, the only attachment is an inspection report for V.A. in Leavenworth, Kansas from Region IV. V.A. Cincinnati agreed to void this now & will resubmit within a month or so.

Colleen C. Casey
Signature

2/11/94
Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☐ No Refund Due

☑ Fee Exempt or Fee Not Required

Comments: 150143

Log completed ☑

Processed by: BAC
3/10/94

9403210138 940211
PDR ADOCK 03002658
C PDR

ML
3P DH

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: EX 7C
EXP. DATE: 19940430
FEE COMMENTS: V
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: V. A. HOSPITAL
   RECEIVED DATE: 940118
   DOCKET NO: 3002658
   CONTROL NO.: 396362
   LICENSE NO.: 34-00799-03
   ACTION TYPE: AMENDMENT

2. FEE ATTACHED
   AMOUNT: ---0---
   CHECK NO.: ---0---

3. COMMENTS

SIGNED P. Dietzopf
DATE 2-2-94

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: ---

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ---
   RENEWAL ---
   LICENSE ---

3. OTHER ---

SIGNED ---
DATE ---

CONVERSATION RECORD

TIME 9:40 and 10am | DATE 2/11/94

TYPE: ☐ VISIT ☐ CONFERENCE ☑ TELEPHONE ☒ INCOMING ☑ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Chris Paul	V.A. Cincinnati, OH.	513-559-5632

ROUTING

NAME/SYMBOL	INT

SUBJECT: C/N 396362 Lic No. 34-00799-03
Amdmt Request

SUMMARY:

I called Chris Paul because Ken Fritz, RSO, is out of the office until Tues. (But Paul reached him at home to discuss this matter). Apparently, somewhere along the V.A. chain the wrong documents were attached to V.A. Cinci. cover letter for this amdmt. No supporting or specific info was received. What was attached was an inspection report for VA - Leavenworth, Kansas from Region IV. In talking with Paul, V.A. Cinci is renewing next month anyhow + it sounded like the correct application for this amendment may have been somewhat deficient. Paul agreed to void this action now + resubmit within the next month or so, as either an amendment again or in the renewal.

ACTION REQUIRED

Void action today.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Casey		2/11/94

ACTION TAKEN

SIGNATURE	TITLE	DATE

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
St Louis MO 63125

In Reply Refer To:

January 7, 1993

U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Arlington, TX 76011

The enclosed correspondence from the Cincinnati, OH VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs
Health Physics Programs (115HP)
915 North Grand Blvd.
St. Louis, MO 63106

Sincerely,

Francis K. Herbig
Health Physics Programs

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3200 Vine Street
Cincinnati OH 45220

In Reply Refer To: 539/115

November 23, 1993

Milton Gross, M.D., Chief Nuclear Medicine
Department of Veteran Affairs Medical Center
Office of the Program Director
Nuclear Medicine Service (111E)
2200 Commonwealth Avenue, Box 7
Ann Arbor, MI 48105

Subject: NRC License Amendment

Enclosed is a request to the NRC for an amendment to our license in order to reduce some radionuclide possession limits and also to purchase and possess up to 100 millicuries of chromium 51 for research and development. Please forward to the NRC. If you have any questions, please contact Kenneth M. Fritz, Radiation Safety Officer, at (513) 559-5632.

John T. Carson
Medical Center Director

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

DEC 22 1993

License: 15-08114-01
Docket: 030-01744

Department of Veterans Affairs
Dwight D. Eisenhower Medical Center
ATTN: James H. Cuer
Medical Center Director
4101 South 4th Street
Leavenworth, Kansas 66048

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-01744/93-01

Thank you for your letter of December 6, 1993, in response to our letter and Notice of Violation dated November 17, 1993. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Sincerely,

Linda Kasner

Linda L. Kasner, Acting Director
Nuclear Materials Inspection Section

cc:
Kansas Radiation Control Program Director

Department of Veterans Affairs
Office of the Program Director
Nuclear Medicine Service
ATTN: Rosemary duFour
24 Frank Loyd Wright Drive
P.O. Box 505 Lobby M
Ann Arbor, Michigan 48106

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

DEC 8 1993

Docket: 030-03255
License: 42-00084-06

Department of Veterans Affairs
Veterans Administration Medical Center
ATTN: Robert F. Stott, Director
2202 Holcombe Boulevard
Houston, Texas 77030

SUBJECT: NRC INSPECTION REPORT 030-03255/93-01 (NOTICE OF VIOLATION)

This refers to the routine, announced inspection conducted by Mr. Mark R. Shaffer of this office on October 12-15, 1993. The inspection included a review of activities authorized by Byproduct Materials License 42-00084-06. At the conclusion of the inspection, the findings were discussed with members of your staff. The enclosed NRC Inspection Report 030-03255/93-01 documents this inspection.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The inspector noted that you have maintained adequate management oversight of the radiation safety program during this inspection interval. The Radiation Safety Committee, through the Radiation Safety Officer, had continued to audit program activities on a regular basis. Based upon the inspector's observations, the audits have been effective in identifying and correcting program deficiencies. Records of licensed activities were adequate for the size and scope of the radiation safety program.

Also reviewed during this inspection were two recent incidents which occurred at your facility. One of these incidents involved the accidental release of xenon-133 gas to the atmosphere in quantities greater than 10 times the limit specified in Appendix B, Table II, Column 1 of 10 CFR Part 20. The second incident relates to a brachytherapy treatment that resulted in a final treatment dose to the patient that was 29 percent less than the prescribed dose. These incidents are described in Sections 4.4 and 9, respectively, of the attached report.

As was discussed with you during the exit briefing, we are continuing our review of the incident involving a brachytherapy treatment with NRC's Office of General Counsel in order to determine whether the incident constitutes a misadministration as defined under 10 CFR 35.2. Following review by regional and NRC headquarters staff, you will be notified of the results of our deliberations.

Also reviewed were the actions you had taken with respect to the violation observed during our previous inspection conducted on November 2-5, 1992. The inspector verified that corrective actions for this violation had been implemented as stated in your reply dated December 29, 1992, and that these actions were effective.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact the inspector identified above at (817) 860-8100.

Sincerely,

Cecil O. Thomas

Cecil O. Thomas, Acting Director
Division of Radiation Safety
and Safeguards

Enclosure:
1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection
Report 030-03255/93-01

cc:
Texas Radiation Control Program Director

Milton Gross, M.D., Director
Nuclear Medicine Service (111E)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

APPENDIX A

NOTICE OF VIOLATION

Department of Veterans Affairs
Veterans Administration Medical Center
Houston, Texas 77030

Docket: 030-03255
License: 42-00084-06

During an NRC inspection conducted on October 12-15, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

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. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on October 14, 1993, licensed material consisting of three vials of hydrogen-3, containing approximately 400 microcuries per vial, located in building No. 109, Room 205, an unrestricted area, was not secured against unauthorized removal and was not under constant surveillance and immediate control of the licensee.

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

B. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

Contrary to the above, as of October 15, 1993, the licensee did not have the apparent exposure rate from a dedicated check source as determined at the time of calibration noted on its Ludlum Model 14C and Victoreen Model 470A survey instruments, and the licensee was using these survey instruments to show compliance with 10 CFR Part 35. Specifically, the exposure rates noted on the instruments were determined by the licensee after they were returned from calibration.

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

C. 10 CFR 35.410 requires that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. This instruction must describe: (1) size and appearance of the brachytherapy sources; (2) safe handling and shielding instructions in case of a dislodged source; (3) procedures for patient control; (4) procedures for visitor

control; and (5) procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

Contrary to the above, on September 25, 1993, one of the licensee's attending physicians cared for a patient undergoing implant therapy and the licensee had not provided the required radiation safety instruction to the physician.

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

Pursuant to the provisions of 10 CFR 2.201, the Department of Veterans Affairs, Veterans Administration Medical Center, Houston, Texas, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas
this 8th day of December, 1993

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-03255/93-01

License: 42-00084-06

Licensee: Department of Veterans Affairs
Veterans Administration Medical Center
2202 Holcombe Boulevard
Houston, Texas 77030

Facility Name: Veterans Administration Medical Center

Inspection At: Houston, Texas

Inspection Conducted: October 12-15, 1993

Inspector: Mark R. Shaffer, Radiation Specialist
Nuclear Materials Inspection Section

Approved: Linda Kasner 12/4/93
Linda L. Kasner, Acting Chief, Nuclear Materials Inspection Section — Date

Inspection Summary

Areas Inspected: Routine, announced radiation safety inspection of licensed activities including the use of byproduct material for: (1) clinical diagnostic and therapeutic nuclear medicine procedures; (2) brachytherapy; and (3) research and development activities conducted under the authorization of the licensee's Radiation Safety Committee.

The inspection included a review of organization, management, and training; personnel monitoring; facilities and instrumentation; materials receipt, preparation, and administration; leak tests and inventory control; radiation surveys and records; waste management and transportation; and the licensee's quality management program. Additionally, this inspection included a review of a brachytherapy incident which occurred at the licensee's facility on September 24, 1993.

Results:

- Within the scope of this inspection, three violations were identified. One of the violations involved a failure to train an individual who

provided care for a patient undergoing brachytherapy treatment. This violation is of concern because the individual attended a patient who had removed a brachytherapy source following implantation and the individual was not properly trained to respond to such circumstances. The individual's failure to respond could have resulted in a significant exposure to a patient and his attending nurses. This item is discussed in Section 9 of this report.

Summary of Inspection Findings:

- Failure to note on radiation detection survey instruments the exposure rate from a dedicated check source as determined at the time of calibration (Section 3).

- Failure to secure licensed material stored in a unrestricted area from unauthorized removal (Section 4).

- Failure to provide radiation safety training to all personnel caring for a patient undergoing implant therapy (Section 9).

Attachment:

- Attachment - Persons Contacted and Exit Meeting

DETAILS

1 PROGRAM OVERVIEW (87100, 83822)

This broad scope medical program includes the use of byproduct material for diagnostic and therapeutic procedures, as well as research activities conducted under the specific approval of the Radiation Safety Committee (RSC).

Routine diagnostic and therapeutic procedures involving the use of radiopharmaceuticals had been performed under the direction and supervision of the Chief of Nuclear Medicine. The nuclear medicine service had performed approximately 250 diagnostic procedures per month. The majority of procedures involved administration of radiopharmaceuticals labeled with technetium-99m. The licensee had received multidose vials of radiopharmaceuticals prepared by a local radiopharmacy. Approximately 40 procedures were performed each year using millicurie quantities of sodium iodide I-131 for thyroid therapy and for whole body scans for metastatic thyroid carcinoma. The licensee had also used strontium-89 as a palliative treatment agent for metastatic bone disease. A separate laboratory located within the nuclear medicine service performed radioimmunoassay procedures.

Brachytherapy procedures were performed under the supervision of an authorized user associated with the licensee's radiotherapy department. During this inspection period five implantations were performed using iridium-192 sealed sources contained in nylon ribbons.

The inspector noted that 20 individuals were approved by the licensee's RSC to conduct research activities using byproduct material. The majority of the research projects conducted during this inspection interval involved labeling cells or protein with microcurie quantities of hydrogen-3, carbon-14, phosphorus-32, sulfur-35, iodine-123, and iodine-131. Additionally, one project involved the analysis of data obtained from cerebral blood-flow studies performed on human subjects using xenon-133 gas. No animal studies had been performed since the last NRC inspection.

1.1 Organization and Management Controls

The organizational structure was found to be as required, and key personnel were as identified in the attachment to this report. The Radiation Safety Officer (RSO), the administrative staff, and the majority of the nuclear medicine staff, department chiefs, and authorized users had been at the facility in their current positions during previous inspections.

A review of the RSC minutes maintained for meetings conducted during this inspection interval revealed that a meeting had been conducted during each calendar quarter as required. The RSC membership included adequate representation from each program area and discussions held during these meetings appeared to include an appropriate range of topics consistent with the size and scope of the licensee's radiation safety program. The committee,

through the RSO and his staff, had performed comprehensive program audits which appeared effective in identifying and correcting deficiencies.

1.2 Personnel Training

The licensee had provided in-service briefings to the technical staff on several occasions since the previous inspection. In addition, training was provided for all ancillary personnel (i.e., nursing, clerical, housekeeping, and maintenance) whose duties involved work activities in areas where radioactive material was used or stored. This training was conducted during new employee orientation and annually thereafter in accordance with Regulatory Guide 10.8, Revision 2, Appendix A.

However, the inspector noted that on one occasion the licensee had not provided adequate radiation safety training to all personnel caring for patients undergoing implant therapy as required by 10 CFR 35.410(a). This item is discussed in Section 9 of this report.

2 PERSONNEL MONITORING (83822 and 87100)

Personal dosimetry devices for whole body and extremity monitoring had been provided to various individuals in accordance with guidance developed by the RSC in order to demonstrate compliance with 10 CFR Part 20. Monitoring devices were exchanged at monthly or quarterly intervals depending upon an individual's work assignment. The majority of devices had been exchanged at monthly intervals.

Quarterly ALARA reviews were conducted by the RSC as required under the license. A review of the licensee's records revealed that occupational exposures were within Level I limits as defined in the licensee's ALARA program and no exposures in excess of regulatory limits had occurred.

During the previous inspection an NRC inspector identified two radiation workers who had failed to use external radiation monitoring devices (finger badges) while dispensing millicurie quantities of technetium-99m. During this inspection, the inspector observed that all nuclear medicine personnel were wearing both whole body and finger badges while preparing and administering radiopharmaceuticals. In addition, research personnel were observed wearing personal monitoring devices where appropriate.

The inspector also reviewed records of bioassays performed for all individuals who participated in the administration of millicurie quantities of iodine-131, as well as for those individuals who had participated in iodination procedures. The licensee's procedures for performing these bioassays appeared adequate and records of bioassay results had been maintained.

3 INSTRUMENTATION AND CALIBRATIONS (83822)

3.1 Dose Calibrator Use

The licensee had maintained two dose calibrators for use in the nuclear medicine department and one dose calibrator for use in the cerebral blood flow research laboratory. The instruments had been used routinely to assay radiopharmaceuticals prior to patient administration.

10 CFR 35.50(b)(1) requires, in part, that the licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the check be performed on a frequently used setting. The licensee had used cesium-137 sealed calibration sources to perform the required constancy checks. Based on examination of radiopharmaceutical preparation and administration records, the inspector determined that the licensee had performed constancy checks as required and that the test results were generally within +/-5 percent of the expected readings.

Each dose calibrator had been tested for accuracy using the appropriate sealed calibration sources and at the required annual frequency as specified in 10 CFR 35.50(b)(2). The most recent accuracy tests were performed during September 1993.

Records of quarterly linearity tests indicated that linearity tests were performed at quarterly intervals, with data obtained over a range of activities that included the highest dosage administered to patients down to approximately 10 microcuries as required by 10 CFR 35.50(b)(3).

It was noted that a geometry test was performed on each dose calibrator during September 1991 in accordance with 35.50(b)(4), and that the instruments had not undergone repair or adjustment since that time.

3.2 Survey Instrument Use and Calibration

The licensee had maintained several radiation detection survey instruments which had been calibrated by an authorized vendor at the required annual frequency. Calibration of the instruments appeared adequate and the exposure rate from a dedicated check source was displayed on each instrument. However, the RSO informed the inspector that the exposure rates displayed on the instruments were determined by the licensee after the instruments had been returned from calibration by the vendor. This was identified as a violation of 10 CFR 35.51(a)(3) which requires, in part, that the licensee conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration.

4 MATERIALS RECEIPT, PREPARATION, AND ADMINISTRATION (87100 and 83822)

As noted in Section 1 of this report, the licensee had received several different radioisotopes for use in clinical diagnostic and therapeutic procedures as well as for use in laboratory research. The licensee had implemented and complied with the package receipt procedures outlined in the license application. Discussions with licensee personnel indicated that personnel involved with the receipt, preparation and administration of byproduct material had received the appropriate training and had complied with applicable licensee procedures.

Although the licensee had generally complied with applicable requirements associated with materials receipt, use, and storage, the inspector identified one violation involving a failure to secure licensed material stored in an area of use. In addition, the inspector reviewed preliminary information concerning the accidental release of xenon-133 to an unrestricted area. Subsequent to the inspection, the licensee provided a written report to NRC describing the incident. The inspector's review of this issue is detailed in Section 4.4 below.

4.1 Preparation and Use Areas

The licensee's facilities for use of byproduct material included the Department of Nuclear Medicine where both diagnostic and therapeutic procedures were performed, a laboratory where radioimmunoassay procedures were performed, the Radiotherapy Department where brachytherapy sources were received and stored, the waste storage and handling area, one building dedicated exclusively to research activities, and various other research laboratories located throughout the medical complex.

4.2 Security of Licensed Material

The inspector observed that the areas noted above were properly posted with appropriate signs and that for the majority of the areas toured during the inspection, adequate measures were in place to prevent an unauthorized individual from entering restricted areas. However, upon entering Building 109 the inspector observed that one research lab, identified as Room 205, was unlocked and unattended. The lab was identified by licensee personnel as an area in which microcurie quantities of hydrogen-3 was used or stored. The inspector noted that the room and the byproduct material contained therein was not secured to prevent unauthorized removal of the material during his tour of the remaining research labs within the building. This observation was confirmed by the licensee's RSO who accompanied the inspector during his tour of the facility. This was identified as a violation of 10 CFR 20.207 which specifies, in part, that licensed material stored in an unrestricted area must be secured from unauthorized removal from the place of storage.

4.3 Preparation and Administration

The licensee's package receipt records indicated that all incoming packages containing radioactive material were properly surveyed. Patient administration records contained all required information, and records of tests performed to determine the molybdenum-99 concentration in technetium-99m elutions used by the licensee indicated concentrations of less than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector observed that syringe shields containing radiopharmaceuticals were properly labeled as required. In addition, the inspector also observed that vials containing radiopharmaceuticals were properly shielded during kit preparation and that personnel were using syringe radiation shields while administering radiopharmaceutical doses to patients.

4.4 Control of Aerosols and Gases

The inspector reviewed records of the licensee's calculated spilled gas clearance times for areas where radioactive xenon-133 gas was used, as well as records of air flow measurements for various rooms and fume hoods. The records were maintained in an orderly fashion and appeared adequate for the licensee's use of radioactive gases. Spilled gas clearance times were posted where required and air flow measurements had been conducted at the required intervals.

As noted in Section 1 of this report, the licensee had one active research project which involved the use of xenon-133 gas to perform cerebral blood flow studies on human subjects. The studies were performed in a research laboratory which was dedicated to the project. Due to the number of studies performed, the laboratory received ampules containing quantities of 500-1300 millicuries of xenon-133 rather than single unit doses. To obtain a single patient dose of 20-30 millicuries from the multidose ampule, the staff used a RADX Xenon-KowII (Kow) which was maintained within a fume hood that was vented directly to the atmosphere. (The Kow is a dispensing device which allows the gas to be withdrawn into a syringe by manipulating a dispensing valve. The valve is manually opened and closed by the user to dispense the required volume and activity of xenon-133.)

During the inspection, the RSO informed the inspector of an accidental release of xenon-133 gas from the Kow which occurred between September 17-19, 1993. According to the RSO, the release occurred when the dispensing valve was inadvertently left in the open position over a weekend period. As a result, approximately 670 millicuries of xenon-133 was allowed to escape from the Kow and was released through the hood exhaust into the atmosphere. The release point for the exhaust is located at the roof top of the building where access is very limited. The licensee maintains constant monitoring of room air concentrations of xenon-133 in the research lab. During the specified period, no increase in xenon-133 concentrations were noted.

According to the licensee's calculations, the release, if averaged over a period of 24 hours, involved xenon-133 concentrations of approximately 60 times the limit specified in Appendix B, Table II, Column 1 of 10 CFR Part 20. However, as this concentration averaged over a period of 1-year does not exceed the applicable limits specified in 10 CFR 20.106(a) it was not identified as a violation.

In accordance with 10 CFR 20.405(a)(1)(v), NRC received a written report, dated October 18, 1993, from the licensee outlining the incident and describing their proposed corrective actions to prevent a recurrence. The licensee's proposed corrective actions, which included color coding the Kow's dispensing valve and providing additional training to workers, appeared to adequately address the problem.

5 LEAK TESTS AND INVENTORY CONTROL (83822)

The licensee possessed several sealed sources which had been used by the nuclear medicine and health physics staffs for calibrating instruments. Several other sealed sources containing microcurie quantities of material were maintained in storage and had not been utilized during this inspection interval.

A review of records associated with the sources indicated that inventories had been conducted at quarterly intervals and the sources were tested for leakage at the required 6-month intervals. Inventory and leak test records contained the model number of each source, and the serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the RSO as required by 10 CFR 35.59(g).

6 RADIATION SURVEYS, RECORDS, AND INDEPENDENT MEASUREMENTS (87100 and 83822)

The licensee is required to perform surveys for removable contamination and ambient radiation dose rates at intervals prescribed under the license and by NRC regulations. The nuclear medicine staff was responsible for performing weekly and daily surveys for removable contamination and ambient dose rates within the nuclear medicine department, and research personnel were responsible for performing monthly surveys within their respective laboratories. The health physics staff had also performed routine surveys during their periodic audits of these areas. Additionally, the health physics staff was responsible for performing surveys within the brachytherapy storage area, the radioactive waste storage and handling room, and all surveys pertaining to patients hospitalized for brachytherapy implant procedures or following the administration of iodine-131 in quantities greater than 30 millicuries.

The licensee had established radiation dose rate trigger levels for area surveys required under 10 CFR 35.70(a)&(b), as well as removable contamination trigger levels for surveys required under 10 CFR 35.70(e). Removable contamination surveys were performed utilizing an appropriate instrument which

had been proven capable of detecting contamination levels as low as appropriate for each isotope, and ambient dose rate surveys were performed using a radiation detection survey instrument with an appropriate meter range.

During this inspection, independent radiation exposure measurements in several areas were performed by the inspector and compared to measurements performed by the licensee. The inspector's survey results proved consistent measurements with those documented by the licensee.

7 WASTE MANAGEMENT AND TRANSPORTATION (87100 AND 86740)

The licensee had used several methods for disposal of radioactive waste material. These included decay-in-storage for solid wastes, disposal to the sanitary sewerage system for certain liquid wastes, and shipment of waste generated by research activities to an authorized disposal site. Additionally, the licensee had returned iridium-192 brachytherapy ribbons to the original vendor following implant procedures. Records associated with disposal via the sanitary sewerage system and decay-in-storage were adequate and contained all required information. Records associated with brachytherapy source transfers and waste shipments properly described the material in a manner specified in Subpart C of 49 CFR Part 172.

8 QUALITY MANAGEMENT PROGRAM (87100)

During this inspection the licensee's implementation of its written quality management (QM) program was reviewed by the inspector. In accordance with 10 CFR 35.32, the licensee had established a written QM program aimed at providing high confidence that byproduct material or radiation from byproduct material would be administered as directed by the authorized user. The inspector observed that the licensee had implemented its program and had instructed all supervised individuals involved in activities subject to 10 CFR 35.32 in the specifics of the program. The licensee had performed an annual review of activities associated with the QM program as required by 10 CFR 35.32(b)(1).

9 BRACHYTHERAPY INCIDENT (87100, 83822)

This inspection also included a review of the licensee's actions taken with regard to a brachytherapy incident which occurred at the facility on September 24, 1993. This incident was reported telephonically to NRC Region IV on September 27, 1993. A written report of the incident, dated October 7, 1993, was also submitted to the regional office for review.

9.1 Incident Summary

On September 24, 1993, one of the licensee's authorized users prepared a written directive for a brachytherapy treatment. The written directive prescribed a total of 36 millicuries of iridium-192, contained in a single nylon ribbon (30 seeds), to be placed in the patient's left endobronchial region for a treatment period of approximately 25 hours. At 3 p.m. CDT on

September 24, 1993, the sources were placed, via an intraluminal pulmonary catheter, such that the patient would receive a palliative treatment dose of approximately 2400 rads to the 95 rads-per-hour isodose line.

Between 7 and 8 a.m. CDT on September 25, 1993, the patient experienced a coughing spasm which displaced the sources from the intended treatment site. The patient coughed the ribbon into his mouth and then removed the ribbon and placed it in a metal tray next to his bedside.

At approximately 8 a.m. CDT a physician visited the patient during morning rounds. This physician was a medical resident from a local university who was assisting the patient's referring physician. At this time the physician was informed by the patient that the sources had become dislodged. Although there was a lead container and forceps within the patient's room, the physician did not attempt to recover the sources. Instead she left the patient's room and informed the nurses that the "sources have been removed." The nurses mistakenly assumed that the physician had intentionally removed the sources and that the ribbon had been placed in its shielded container. The RSO nor the authorized user were notified of the source removal at this time.

At 4 p.m. CDT on September 25, 1993, the licensee's authorized user and medical physicist arrived at the patient's room to remove the sources at the originally prescribed time. Upon entering the room with a radiation detection survey instrument, the physicist noted an exposure level higher than expected and immediately observed that the patient's catheter containing the sources was not secured to the patient as would be expected. Additionally, it was noted that the patient's wife and another visitor were in the patient's room. The visitors were asked to leave the room. The physicist then located the ribbon containing the sources within the steel tray and placed the ribbon in the lead container.

The visitors were later questioned as to how long they had been in the patient's room during an interview conducted by the medical physicist. The visitors stated that they had only been in the room for approximately 10 minutes. Except for brief visits by the patient's attending nurses, no other hospital personnel or visitors entered the patient's room.

9.2 Post-Incident Followup Actions

As a result of patient intervention, the total treatment time was reduced from 25 hours to 18 hours. This resulted in a treatment dose that was 29 percent less than the prescribed treatment dose (1710 centigray rather than the prescribed 2400 centigray). In addition to the dose delivered to the treatment site, the licensee calculated a dose of approximately 1 centigray for the patient's oral cavity and approximately 0.156 centigray for a whole body dose for the patient. These calculations were based upon assumptions that the sources were in the patient's mouth for only a few seconds and located next to the patients bedside (1 meter) for 9 hours. The dose to the visitors for the 10 minutes that they were in the room was assumed to be negligible.

During the inspection, the inspector interviewed licensee personnel involved with the brachytherapy procedure. Personnel interviewed included the authorized user, the medical physicist, the RSO, the nursing staff, and a member of the licensee's internal administrative investigation team.

The inspector's review of training provided by the RSO revealed that the nursing staff had been given the appropriate radiation safety instructions regarding brachytherapy implants as required by 10 CFR 35.410(a). This instruction included a description of the size and appearance of the sources, safe handling and shielding in case of a dislodged source, procedures for visitor control, procedures for notification of the RSO, and proper use of pocket dosimeters to monitor their exposure. The inspector's interviews with the nursing staff caring for the patient indicated that the staff had an adequate understanding of radiation safety relative to the procedure.

However, the RSO stated that he had not provided similar instructions to the referring physician who had checked in on the patient. This was evidenced by the physician's failure to retrieve the sources or notify the RSO that they had become dislodged following her discovery of the incident. Although the physician was a resident in training and may have received some radiation safety training through the university, the RSO stated that the licensee had not provided the physician with radiation safety instructions specific to those individuals caring for patients undergoing implant therapy. The was identified as a violation of 10 CFR 35.410(a) which requires, in part, that a licensee provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy.

Additionally, the inspector noted an item of concern during his interview with one of the patient's attending nurses. This individual stated that although the RSO had instructed her in the proper use of pocket dosimeters, she had chosen not to wear the device while caring for the patient. She stated that she felt the devices were not very accurate and therefore not worth wearing. Furthermore, a review of records associated with other patients who had undergone radiopharmaceutical therapy while the nurse was in attendance revealed that she may have chosen not to wear a pocket dosimeter for other cases as well. The inspector noted that the licensee's procedures manual specifies that dosimeters will be provided to all nurses caring for implant therapy patients and that these dosimeters should be worn. However, the RSO stated that these dosimeters are provided for health physics purposes and were not provided to comply with 10 CFR 20.101.

Although the issue was not identified as a violation, it was discussed with the licensee's RSO and noted as an item worthy of further review. Prior to completion of the inspection, the licensee responded to this concern with disciplinary action for the nurse as well as plans to provide direct supervision for the nurse during future procedures where dosimeters are to be utilized.

10 FOLLOWUP ON CORRECTIVE ACTIONS FOR VIOLATIONS (92702)

10.1 (Closed) Violation 030-03255/92-01: Failure to make surveys to assure compliance with that part of 10 CFR 20.101 that limits that radiation exposure to worker's extremities

Following the last inspection conducted on November 2-5 1992, the licensee had provided extremity monitors to all individual that the RSC deemed appropriate, and had performed periodic audits to ensure their continued use.

ATTACHMENT

1 PERSONS CONTACTED

1.1 Licensee Personnel

T. Ashizawia, M.D., Authorized User, Research
C. Bennett, LVN, Nursing
E. Brown, RN, Nursing
E. Butler, M.D., Chief, Radiotherapy Service
M. Franklin, AA/Radiotherapy Service
J. Haidacher, Research Assistant
S. Hooks, Health Physics Staff
J. Hrbolich, Research Assistant
*N. Kutka, M.D., Chief, Nuclear Medicine Service
A. Laughter, Research Assistant
L. Liem, M.D., Authorized User, Radiotherapy
J. McNew, Nuclear Medicine Technologist
V. Montecillo, RN, Nursing
F. Orson, M.D., Authorized User, Research
S. Simole, Research Assistant
*R. Stott, Medical Center Director
T. Teslow, Ph.D., Medical Physicist
T. Timme, Research Assistant
D. Travis, Health Physics Staff
*J. Triebel, Radiation Safety Officer
*A. Walmus, Associate Medical Center Director
P. Wills, Research Assistant
*E. Young, M.D. Chief of Staff

1.2 NRC Personnel

*Mark R. Shaffer, Radiation Specialist

*Denotes individuals present during site exit briefing on October 15, 1993.

2 EXIT MEETINGS

A site exit briefing was conducted on October 15, 1993, with those individuals identified in Section 1. The inspector reviewed the specific findings as noted in the report. Additionally, the inspector informed the licensee that NRC's review of the brachytherapy incident described in Section 9 of this report would be ongoing in order to determine whether the incident constitutes a misadministration as defined in 10 CFR 35.2. The inspector noted that following review by regional and NRC headquarters staff the licensee would be notified of the results of NRC's deliberations.

34-00799-03
030-02658
4-30-94
EXTC

DATE: 1/26

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: John

LICENSEE: V.A.

LICENSE NUMBER:

MAIL CONTROL NUMBER:

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Pat Dietloff, as soon as possible.

☐ Additional Information to Control No. _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No._____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not been started.

☑ Appears to be a(n) Amendment for Cincinnati, OH, VA. Medical Center.

☐ Other: Its unclear to me which facility is to be amended. I've highlighted the address

Thanks For Your Help!!!

CONTROL NO. 396362