U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Reports No. 030-00302/89001(DRSS); 030-02274/89001(DRSS)

Docket Nos. 030-00302; 030-02274 Licenses No. 24-00481-04; 24-00481-05

Categories: G3; G

Priorities: I; III

Licensee: Ellis Fischel State Cancer Center (EFSCC)
115 Business Loop 70 West
Columbia, MO 65201

Inspection At: 115 Business Loop 70 West
Columbia, MO 65201

Inspection Conducted: April 4-5, 1989

Enforcement Conference: April 25, 1989

Inspectors: C. C. Casey
Radiation Specialist — Date: 5/11/89

C. F. Frazier
License Reviewer — Date: 5/11/89

Reviewed By: D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2 — Date: 5/11/89

Approved By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch — Date: 5/11/89

Inspection Summary

Inspection on April 4-5, 1989 (Reports No. 030-00302/89001(DRSS); 030-02274/89001(DRSS))

Areas Inspected: This special unannounced inspection was performed in response to irregularities in personnel changes identified by a license reviewer in the May 25, 1989 renewal application for the 24-00481-05 license. The reviewer subsequently learned that the licensee was using an unauthorized Radiation Safety Officer, that the licensee had no authorized user for the teletherapy license and the Chairman of the Radiation Safety Committee had been two

unauthorized individuals since February 1985. The inspection included a review of the licensee's organization; enforcement history; training; radiological protection procedures; facilities; security of licensed materials; instrumentation; personnel radiation exposure control; sealed source inventory and leak tests; internal audits; molybdenum-99 breakthrough tests; radioactive package receipt and surveys; area surveys; waste disposal; teletherapy monthly spot checks and annual full calibrations; notifications and reports; postings and labelings; and independent measurements.
Results: Of the areas inspected, 12 violations and seven areas of concern were identified:

1. License No. 24-00481-05

   a. License Condition No. 19 of Amendment No. 35 - individuals who were not approved by NRC acted as Chairpersons of the Radiation Safety Committee (Section 5).

   b. 10 CFR 35.13(c) - failure to obtain an amendment to the license prior to changing Radiation Safety Officers (Section 5).

   c. 10 CFR 35.13(e) - failure to obtain an amendment to the license prior to changing location of the waste storage area (Section 5).

   d. 10 CFR 35.204(b) - improper implementation of the molybdenum-99 breakthrough test procedure (Section 5).

   e. 10 CFR 35.315(a)(8) - personnel who prepared and administered therapy doses of iodine-131 were not assayed for thyroid burden (Section 6).

   f. 10 CFR 35.315(a)(4) - failure to measure dose rates in certain restricted and unrestricted areas after patients had received radiopharmaceutical therapy (Section 5).

   g. 10 CFR 35.22(a)(2) - Radiation Safety Committee failed to meet during the third quarter of 1988 (Section 5).

   h. 10 CFR 19.13(b) - an individual was not provided with information regarding exposure to radiation in spite of repeated requests for this information (Section 6).

2. License No. 24-00481-04

   a. License Condition No. 12.A of Amendment No. 31 - unauthorized physicians used licensed material (Section 5).

   b. 10 CFR 35.615(d)(3) - failure to test teletherapy radiation monitors with a dedicated check source (Section 5).

   c. 10 CFR 35.615(d)(1) - failure of a teletherapy radiation monitor to provide visible notice of a partially exposed source (Section 5).

d. 10 CFR 20.401(a) - failure to record complete NRC Form-5 information for one individual (Section 6).

3. Areas of Concern

a. There is a need for adequate management staff oversight of both licensed programs to assure safe operations and compliance.

b. It appears that the Radiation Safety Officer (RSO) does not have sufficient time to devote to the radiation safety programs due to extensive patient care related duties in medical physics.

c. The three physics technologists have to use spare ring badges that are not in their names - concern was raised about control of these badges and potential exposure tracking problems.

d. It appears that there is a need to assure an atmosphere where employees can freely raise safety concerns without fear of reprisal.

e. The cobalt-60 source in the Picker Model 6096A teletherapy unit malfunctioned on April 4, 1989 - does the licensee plan to repair or dispose of the unit?

f. The TV screen display for the Theratron 80 was scrambled as of April 4, 1989 - concern was raised regarding whether it had been repaired.

g. A therapy technologist hired April 1988 had to use an extra spare badge for four months before obtaining a badge in his own name. Concern was expressed regarding the potential for problems with control of such badges and tracking the exposures they record.

DETAILS

1. Persons Contacted

*+Ronald G. Vincent, M.D. Medical Center Director
*+Denise J. Noonan, Ph.D., Radiation Safety Officer (RSO) and Senior Medical Physicist
+Jaya Soni, M.D., Chairperson, Radiation Safety Committee
Olin Smith, Nuclear Medicine Technologist
Kay Glass, Radiation Therapy Technologist
William White, Medical Physicist

+Denotes preliminary exit interview attendees on April 5, 1988.
*Denotes enforcement conference attendees on April 25, 1989.

2. Purpose of Inspection

This special unannounced inspection was performed in response to irregularities in personnel changes identified by a license reviewer in the May 25, 1988 renewal application for the 24-00481-05 license. The followup inspection addressed issues pertaining to the irregularities in the personnel changes as well as elements normally addressed in a routine inspection.

3. Organization

Ronald G. Vincent, M.D., Medical Center Director
Denise J. Noonan, Ph.D., Radiation Safety Officer
Jaya Soni, M.D., Chairperson, Radiation Safety Committee
Mary Lee, M.D., Authorized User
George Wilson, M.D., Authorized User
Charles Blackwell, M.D., Authorized User
Thomas Sullivan, M.S., Teletherapy Physicist (as of April 26, 1989)

The nuclear medicine technologist reports to Drs. Soni, Lee, Wilson, and Blackwell. The therapy technologists report to Dr. Lee. All technologists also report to Dr. Noonan, for purposes of the licensed programs. Dr. Noonan reports to the Radiation Safety Committee and directly to Dr. Vincent.

4. Licensed Programs and Enforcement History

a. 24-00481-05 license: License was originally issued on September 7, 1965. License became a Type A broad scope with Amendment No. 31 dated December 16, 1977. The license was renewed in its entirety on January 25, 1989 via Amendment No. 38, which also removed its broad scope authority. They are currently authorized to use byproduct material in 10 CFR 35.100, 35.200, 35.300, and 35.400, and materials identified in 10 CFR 31.11 (kits). They currently perform 60-80

studies per month, about 98% of which use technetium-99m related products. About 10 patients per year are treated with <30 millicuries (mCi) iodine-131 as capsules and 0-4 patients per year are treated with 30-300 mCi iodine-131 as capsules. About 4 brachytherapies are performed per year, mostly with radium (disposed of 3/89) and rarely with iridium-192. Cesium-137 sources have been ordered. One 1.3 Ci molybdenum-99/technetium-99m generator is received each week.

The enforcement history for License 24-00481-05 includes:

(1) Last inspection on April 14, 1987, no violations identified.

(2) Inspection on February 4-5, 1985, 3 violations and 1 area of concern (intimidation), violations as follows: failure to lock the nuclear medicine hot lab when unattended; failure to calibrate a survey meter on annual basis; failure to survey elution and preparation areas during certain months.

(3) Inspection on June 7-10, 1982, no violations identified. This inspection also examined allegations received in March 1981:

(a) Dummy iridium seeds placed on the chairs of the radiation safety staff.

(b) Sabotage of office equipment with foul smelling substance.

(c) Intimidation and harassment of the radiation safety staff.

These problems appeared to have been resolved during inspection.

(4) 1978-1980 - "the Richter case" - the licensee released a patient who still contained 4 implanted Ir-192 seeds. Their then RSO (Dr. Richter) notified NRC, was subsequently fired for making the report and the courts ruled the licensee violated 10 CFR 19.16(c) in discharging him.

(5) Inspection on January 17-18, 1980, 3 violations identified: failure to issue film badges at monthly intervals; failure to record extremity exposures to an individual; failure to properly record personnel radiation exposures in accordance with Form NRC-5. (Performed in response to allegations regarding improper changing of film badges and workers overexposed from radium and P-32 therapies.)

b. 24-00481-04 license: License was originally issued on July 6, 1962 and was last renewed in its entirety on June 6, 1988 via Amendment No. 31. Two teletherapy units are authorized for medical use as described in 10 CFR 35.600. The Picker Model 6096A is authorized for 5000 Ci but contains 1115 Ci and has not been used on patients

since February 2, 1989. It is used as a backup unit normally. The AECL Theratron 80 is authorized for 5500 Ci but contains 2440 Ci and has not been used on patients since February 9, 1989, due to lack of a teletherapy physicist. The Picker was normally used for one patient every 3 months. The Theratron was used as backup for the licensee's Siemens accelerator and was used on about 15 patients for about 4 days per month.

The enforcement history for License 24-00481-04 includes:

(1) Last inspection on April 4, 1987, no violations identified.

(2) Inspection on February 4-5, 1985, no violations identified.

(3) Inspection on June 7-10, 1982, no violations identified.

(4) Inspection on September 5-6, 1979, one violation, failure to leak test sealed cobalt-60 source in timely manner.

(5) April 29, 1980 - Immediate Action Letter issued stopping use of Picker unit until re-calibrated.

5. Routine Inspection Elements

Routine inspection elements for both licensed programs were included in the inspection.

The licensee's internal audits for the nuclear medicine program consist of quarterly visits from their consultants, Radiation Consultants of Mid-America. Reports resulting from these audits were reviewed and the scope of each audit appeared to be comprehensive. However, although the consultant noted several minor potential problem areas, none of the violations identified by the NRC inspector during this inspection were found by the consultant prior to inspection.

The licensee's training program appears to be generally adequate. The licensee uses videos, slides, handouts, lectures, one-on-one discussions, audio cassettes from the Society of Nuclear Medicine, NRC publications, and periodic "dry-run" drills for teletherapy as training tools. Personnel interviewed appeared to be well-trained and were aware of their rights and responsibilities as radiation workers according to 10 CFR 19.12. Training includes the ancillary staff, as appropriate, and records of training were maintained and reviewed, particularly therapy patient training for caregivers, as specified in 10 CFR 35.310 and 10 CFR 35.410. Records showing training for teletherapy personnel according to 10 CFR 35.610 were reviewed and found to be adequate. Retraining sessions are offered at least annually and all training is coordinated through the RSO and consultants.

Minutes from Radiation Safety Committee (RSC) meetings were reviewed from 1987-1989. Until January 25, 1989, the licensee had a Type A broad scope license but no new authorized users were approved and the

research program was inactive. Membership of the Committee appears adequate with one exception. One of the main functions of the RSC is to administer the institution's radioactive material program including the approval and disapproval of proposed radioactive materials users and uses. The Chairman of the RSC has an essential radiation safety function in that he or she directs the charter for the RSC. License Condition 19 of Amendment 35 for the 24-00481-05 license requires the licensee to use material in accordance with statements, representations, and procedures contained in a letter dated May 2, 1983. The letter dated May 2, 1983 states that Jose Pacheco, M.D. would be Chairman of the Radiation Safety Committee. However, on February 22, 1985 Dr. Jose M. Sala became the Chairman of the RSC and in July 1988 Dr. Jaya Soni became the Chairperson of the RSC. Neither Dr. Sala nor Dr. Soni were approved by NRC to chair the RSC. This constitutes a violation of License Condition 19 of Amendment No. 35 for the 24-00481-05 license which requires the Chairman of the RSC to be Jose Pacheco, M.D.

RSC meetings have been held quarterly with the exception of the third quarter of 1988 when a meeting was not held. This constitutes a violation of 10 CFR 35.22(a)(2) which requires that each medical institution establish a Radiation Safety Committee to oversee the use of byproduct material and requires the Committee to meet quarterly.

Staffing for both licensed programs was reviewed. 10 CFR 35.13(c) requires that a licensee obtain an amendment prior to changing its Radiation Safety Officer (RSO). License Condition No. 12C of Amendment No. 37 for the 24-00481-05 license and License Condition No. 11 of Amendment No. 31 for the 24-00481-04 license require the RSO to be Jose Maria Sala, M.D. However, during the period from July 1, 1988 through January 25, 1989 the licensee had no authorized RSO. This constitutes a violation of 10 CFR 35.13(c) which requires that a licensee obtain an amendment prior to changing its RSO.

License Condition No. 12A of Amendment No. 31 for the 24-00481-04 license names Jose M. Sala as the authorized user. However, from July 1, 1988 through January 25, 1989, two physicians other than Jose M. Sala, M.D. functioned as authorized users, including prescribing cobalt-60 teletherapy treatments for humans (Attachment A). Both physicians' credentials were reviewed and both were found to be qualified to administer cobalt-60 teletherapy treatments for humans. This constitutes a violation of License Condition No. 12A of Amendment No. 31 for the 24-00481-04 license which names Jose M. Sala as the authorized user.

The licensee's radiological protection procedures appeared to be adequate in that they included the use of protective clothing, disposable gloves, vial and syringe labels and shields, assaying of patient doses prior to administration, and other protective measures.

Leak tests and inventories for the licensee's sealed sources, including two cobalt-60 teletherapy sources and several submillicurie dose calibrator reference sources, appeared to be adequate. The inspectors noted, however, that the licensee used a radium-226 standard to obtain efficiency when counting and calculating leak tests for the cobalt-60

sources. The inspectors suggested that the use of a cobalt-60 standard, which the licensee possessed, would yield better test results. The licensee agreed to consider this suggestion.

The licensee possesses a variety of survey instruments, including a Keithley digital ionization chamber. In addition, the licensee possesses an electrometer and chambers sufficient to perform required output tests and calibrations on the two cobalt-60 teletherapy units. K and S Associates calibrates the electrometer and chambers, which was last performed on February 6, 1989. Radiation Consultants of Mid-America calibrates the survey instruments for nuclear medicine and the licensee calibrates its own survey meters in-house for the teletherapy license. These calibrations appeared to be adequate.

The licensee also possesses two Eberline ESI 2 radiation monitors, one for each of its two cobalt-60 teletherapy rooms. Both monitors have a backup battery power supply. 10 CFR 35.615(d)(3) requires that a licensee install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status. Each radiation monitor must also be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients. In addition, 10 CFR 35.615(d)(1) requires that a radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. Although the licensee possesses the required radiation monitors, they were not checked with a dedicated check source for proper operation on each day of use from April 14, 1987 through April 5, 1989. The monitors were checked once per month during this time. On April 4, 1989 the Picker Model 6096A teletherapy source malfunctioned and remained partially exposed for approximately ten minutes. However, the radiation monitor failed to provide visible notice of this malfunction, in that its green lights were lit ("safe condition - beam off") instead of its red lights ("unsafe condition - beam on"). The failure to test each radiation monitor with a check source each day prior to use of the teletherapy units on patients and the failure of the radiation monitor to provide visible notice of a partially exposed source constitute violations of 10 CFR 35.615(d)(3) and 10 CFR 35.615(d)(1), respectively.

The licensee's procedures and records for receiving and surveying packages of radioactive material were reviewed and found to be adequate. No packages with unusual radiation levels or significant contamination have been received, according to the nuclear medicine technologist.

The licensee uses a 1.3 curie generator, received weekly, to obtain its technetium-99m. Tests of the licensee's dose calibrator, including accuracy, linearity, and constancy checks, appeared to be adequate. When asked by the inspector, the nuclear medicine technologist (NMT) stated that he tested each eluate for molybdenum-99 contamination and recorded the results. During the inspector's review of the molybdenum-99 test records and procedures, it became apparent that the licensee was not calculating molybdenum-99 concentration correctly. The licensee uses a Squibb CRC-17 radioisotope dose calibrator (Attachment B) whose molybdenum-99 (moly) assay procedure requires that the net moly reading

be multiplied by a correction factor (to correct for canister shielding effects) and then divided by the technetium-99m activity to obtain moly-99 concentration. The NMT told the inspectors, when asked, that he had never used the correction factor to correct his moly reading for canister shielding effects. Therefore, his readings from April 14, 1987 through April 5, 1989 were calculated too low by a factor of 3.5. The improper implementation of the moly assay procedure constitutes a violation of 10 CFR 35.204(b) which requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum concentration in each eluate. The inspectors re-calculated one moly assay per month from April 1987 through March 1989 using the 3.5 correction factor and did not find a value higher than the Part 35 limit of 0.15 microcuries moly-99 per millicurie technetium-99m.

The licensee's area survey procedures and records were reviewed for the nuclear medicine program. The licensee appears to be performing its daily surveys, weekly surveys, and weekly wipe tests in accordance with 10 CFR 35.70. The inspector suggested that the licensee take more than just one wipe test sample each week. The licensee agreed to consider this suggestion. The licensee's surveys for patients receiving radiopharmaceutical and brachytherapy treatments were reviewed. As the licensee has cesium-137 therapy sources on order and very rarely performs an iridium-192 inplant, the inspectors focussed on radiopharmaceutical therapies. 10 CFR 35.315(a)(4), requires that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75, a licensee shall, promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement instrument to demonstrate compliance with the requirements of 10 CFR 20. However, the licensee failed to perform these required surveys for patients who received radiopharmaceutical therapy as follows: 106.8 millicuries on 4/25/87; 211.4 mCi on 5/20/87; 207 mCi on 8/3/87; 313 mCi on 9/21/87; 101.4 mCi on 10/19/87; 263 mCi on 12/21/87. This constitutes a violation of 10 CFR 35.315(a)(4) which requires that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75, a licensee shall promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement instrument to demonstrate compliance with the requirements of 10 CFR 20.

The licensee's facilities were inspected, including the nuclear medicine department, both cobalt-60 teletherapy rooms, areas adjacent to the teletherapy rooms, and the waste storage areas. Security and access control to these facilities appeared to adequately prevent access by unauthorized persons. The hot lab, waste areas, and teletherapy rooms are locked unless in use and the keys are stored remotely. The teletherapy rooms each had viewing windows, television camera viewing systems, door interlocks, door lights indicating beam status, and appropriate emergency response instructions posted at the console area. Door and console interlocks were tested by the inspectors and found to be adequate except for the Picker Model 6096A unit, whose source remained partially open for about ten minutes during the demonstration. The source subsequently

retracted and the room was locked. The licensee agreed to not use the Picker unit until it had been repaired and calibrated, as verified in a Confirmatory Action Letter issued by Region III to EFSCC on April 14, 1989 (Attachment C). Postings and labelings required by 10 CFR 19 and 20 were in evidence throughout the facilities and appeared to be adequate. The licensee's handling of recent experiences, if any, with misadministrations, thefts and losses, incidents, notifications, and reports were reviewed and found to be adequate.

During the inspection, it became apparent that the licensee had added a waste storage facility that was not approved in the license. This constitutes a violation of 10 CFR 35.13(e) which requires that a licensee obtain a license amendment before it adds to or changes the areas of use identified in the application or on the license. Application for the 24-00481-05 license dated May 25, 1988 requires that wastes be stored in Room No. 143. However, on March 31, 1989, the licensee began using Room 26 for storage of spent generators and radioactive wastes in addition to Room No. 143, without benefit of an amendment to the license.

The licensee's waste disposal procedures, surveys, and records were reviewed and found to be adequate. Most radwaste consists of spent generators and various dry solids, such as syringes, needles, vials, gloves, and paper contaminated with technetium-99m products. Occasionally, non-byproduct materials are used. Wastes are segregated according to half-life when appropriate and stored until background levels are reached. The licensee then surveys the wastes, defaces labels, and disposes of them as normal trash. Generators are stored for 18 weeks and then returned to the vendor. The iriduim-192 seeds from a rare implant are held for decay or re-used or returned to the vendor. Wastes accumulated from a hospitalized iodine-131 therapy patient are held for decay until they reach background levels and then surveyed and discarded. Liquid wastes are not generated to a significant degree. No radioactivity in effluents is released to unrestricted areas.

During inspection of the teletherapy program, full calibration and monthly spot check procedures and records were reviewed. Full calibrations are performed annually, usually in April, by an authorized teletherapy physicist. The full calibrations reviewed included parameters listed in 10 CFR 35.632 and appeared to be adequate. Spot checks have been performed monthly, as required, and included parameters described in 10 CFR 35.634. American Association of Physicists in Medicine (AAPM) procedures are employed. An output check on the Picker Model 6096A unit in April 1988 measured 35.16 rads per minute, which was within 1% of the calculated exposure. An output check on the Theratron 80 on February 24, 1989 showed 59.58 rads per minute measured versus 59.629 rads per minute calculated, which is within 1% error. The licensee participates in protocol tests through M. D. Anderson Hospital in Houston, an AAPM - Radiological Physics Center, but the RSO could not locate these records during the inspection. No spot checks were performed on either unit during March 1989 due to a temporary vacancy in the teletherapy physicist

position. No patients were treated on either unit during this time. On April 26, 1989, Tom Sullivan, M.S., was authorized by NRC to be the teletherapy physicist.

A written prescription for teletherapy treatment signed by a therapy physician is used. The technologists perform the initial dose calculations on computer and treatment begins. Before the second treatment, Dr. Noonan and/or Mr. White checks these calculations. The chart is then checked weekly until treatment is concluded and a final chart check of treatment parameters, especially given or "delivered" dose is performed. No misadministrations have occurred since the previous inspection April 14, 1987. The inspection and servicing required by 10 CFR 35.647 was last performed on the Theratron 80 March 10, 1988 and on the Picker 6096A in February 1985 by Neutron Products, Inc. When problems occur with the units, the licensee obtains services from authorized persons. No cobalt-60 sources have been transferred since the last inspection.

Independent measurements were performed using an NRC Xetex 305B, S/N 013167 as follows:

a. Picker 6096A teletherapy unit - all areas surrounding the head measured 2 millirem per hour (mR/hr) or less at one meter; during "beam on," adjacent area surveys were 0.1-0.2 (background) except for 1.6 mR/hr at the common wall in the Theratron room and 0.5 mR/hr at the surface of the viewing window near the console.

b. Theratron 80 teletherapy unit - all areas surrounding the head measured 2 mR/hr or less at one meter; during "beam on," adjacent area surveys were background except for 0.9 mR/hr at the wall of the adjacent wipe room.

c. Hot Lab - 0.2 mR/hr at standing distance from generator (shielded) and 0.5 mR/hr at standing distance from shielded waste.

d. Waste Storage Room No. 26 - 0.2-0.4 mR/hr at standing distance from spent generators.

Nine violations were identified.

6. Personnel Radiation Exposure Control

a. External Exposures

The licensee provides film badges and thermoluminescent dosimeters (TLDs) to measure radiation dose to each radiation worker's whole body and extremities (hands). On August 1, 1988, the licensee changed its badge supplier from Landauer to Siemens, both NVLAP accredited vendors. Badges are furnished and processed on a monthly frequency. The RSO reviews reports on receipt and has begun to post them. The inspectors reviewed exposure reports from December 1987 through February 1987. On the nuclear medicine license, the highest annual whole body reading recorded was 660 millirem and the highest

annual extremity dose recorded was 7280 millirem. On the teletherapy license, the highest annual whole body dose recorded was 60 millirem, whi may have included radium-226 and/or accelerator exposure. No do exceeding NRC limits were observed.

NRC Form 5 data was complete for all badged individuals except one. Records for a therapy technologist, whose badge incept date was August 1988, did not indicate his social security number and date of birth, which is information required by NRC Form 5 in accordance with 10 CFR 20.401(a). This constitutes a violation of 10 CFR 20.401(a) which requires that each licensee maintain records showing radiation exposures on Form NRC 5 or on clear and legible records containing all the information required by Form NRC 5.

During the inspection, a radiation worker told the inspectors that, on several occasions during the period from April 14, 1987 through late February 1989, he had requested his radiation exposure records, but was not advised of his radiation exposure. The worker indicated that some of his requests had been made at least one year apart. The inspectors reviewed personnel exposure reports for this individual and confirmed that he was badged and received exposures to both his whole body and extremity badges during this time. The individual stated that he had requested these records from the former Radiation Safety Officers, who no longer work for EFSCC. Neither the current RSO nor the Medical Center Director were able to dispute this individual's claim that he had not been provided with his radiation exposure records during the period from April 14, 1987 through late February 1989. This constitutes a violation of 10 CFR 19.13(b) which requires that at the request of any worker each licensee shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the license pursuant to 20.401(a) and (c).

b. Internal Exposures

At EFSCC, internal exposure could occur from the preparation or administration of radioactive iodine-131 in therapeutic quantities which would require hospitalization of the patient, i.e., activities of 30 millicuries or more. On six occasions in late 1987, the licensee administered dosages of more than 30 millicuries of encapsulated iodine-131 to patients, but did not perform bioassay measurements on the staff who prepared and administered these dosages to determine whether any accidental uptake had occurred. This constitutes a violation of 10 CFR 35.315(a)(8) which requires that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75, a licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage. These dosages of iodine-131 were administered as follows: 106.8 mCi on 4/25/87; 211.4 mCi on 5/20/87; 207 mCi on 8/3/87; 313 mCi on 9/21/87; 101.4 mCi on 10/19/87; 263 mCi on 12/21/87.

Three violations were identified.

7. Exit Interview

An exit interview was held on April 5, 19[illegible] with Dr. Vincent, Dr. Soni, and Dr. Noonan. The apparent violations [illegible]reas of concern, and other recommendations were discussed as well a[illegible] the NRC policy regarding possible escalated enforcement.

8. Enforcement Conference

An Enforcement Conference was held in the Region III office on April 25, 1989. The licensee was represented by Dr. Vincent and Dr. Noonan of Ellis Fischel State Cancer Center. The NRC was represented by Mr. A. Bert Davis and others of the Region III staff. The licensee was informed that the violations are being considered in the aggregate for escalated enforcement action. During the meeting, the NRC enforcement policy and the proposed violations and areas of concern were discussed. The licensee presented their conclusions and corrective actions. The licensee acknowledged the proposed violations and concerns and believes that their planned corrective actions will preclude future noncompliance. Mr. Davis requested that the licensee respond to NRC within one week regarding whether they would be retaining an outside consultant's assistance to review their entire radiation safety program. The response should also include a brief description of the RSO's duties to reflect whether she is being allotted sufficient time to devote to the radiation safety program.

Attachments:
A. EFSCC treatment plans
B. Squibb Moly Check Procedure
C. CAL to EFSCC dated 4/14/88

ATTACHMENT A,

Treatment Planning

ELLIS FISCHEL STATE CANCER CENTER
Columbia, Missouri 65203

Weinzeel, Mary
538583

88-F-0

Neck: Rt side, metastatic Ca. lymph nodes.

X DEFINITIVE O PALLIATION O PREOP O POSTOP O PROPHYLACTIC

	1	2	3	4	5	6
Unit	Theta					
Quality	1.25 MV					
Site	Rt neck					
Dose	1800					
Daily Tumor Dose	200					
Fractions	9					
Duration (wk)	1+					
Treatment Days per week (., 2, 3, 4, 5)	5					
Boost Plan	?					
Field Arrangement	IAP=PA-					

1. Appositional
2. AP-PA-Rt & Lt Lat.
3. Three Field
4. Box
5. SAD/SSD
6. Rotation
7. Wedge
8. Tangential

COMMENTS:

Depths	much					

X Simulation O Clinical X Individual Blocking O Cast O Bolus O Contour O Computer Plan O Split Course
O Re-evaluation O Spinal Cord _____ O Rest

Weekly CBC

Date 7-20-88

Radiation Oncologist [signature]

ATTACHMENT A-2

Treatment Planning

ELLIS FISCHEL STATE CANCER CENTER
Columbia, Missouri 65203

Greer, Lovada
535010

42 - F - N

Breast: Rt. side locally advanced disease.

O DEFINITIVE X PALLIATION O PREOP O POSTOP O PROPHYLACTIC

	1	2	3	4	5	6
Unit	Picker 5000					
Quality	1.25 MV.					
Site	Rt. breast	Rt. supra axilla.				
Dose	3000	3000				
Daily Tumor Dose	200	200				
Fractions	15	15				
Duration (wk)	3	3				
Treatment Days per week (1, 2, 3, 4, 5)	5	5				
Boost Plan	?	?				
Field Arrangement	AP direct	AP direct				

1. Appositional
2. AP-PA-Rt & Lt Lat.
3. Three Field
4. Box
5. SAD/SSD
6. Rotation
7. Wedge
8. Tangential

COMMENTS:

Depths	Dmax	Dmax				

O Simulation X Clinical O Individual Blocking O Cast O Bolus O Contour O Computer Plan O Split Course
O Re-evaluation O Spinal Cord _____ O Rest

Weekly cbc.

Date 7-7-88

Radiation Oncologist [signature]

Treatment Planning

ELLIS FISCHEL STATE CANCER CENTER
Columbia, Missouri 65203

Kresl, Geraldine
539228

45 - F - N

Head and Neck: oral tongue, lt. side. Sq cell ca.
S/P hemiglossectomy.

X DEFINITIVE O PALLIATION O PREOP O POSTOP O PROPHYLACTIC

	1	2	Boost. 3	4	5	6
Unit	Thera.	Thera.	Thera.			
Quality	1.25 MV.	1.25 MV.	1.25 MV.			
Site	Head & neck.	Lat. Supra cl.	Head & neck.			
Dose	4000	5000	1000			
Daily Tumor Dose	200	200	200			
Fractions	20	25	5			
Duration (wk)	4	5	1			
Treatment Days per week (1, 2, 3, 4, 5)	5	5	5			
Boost Plan	Yes.	NO	NO.			
Field Arrangement	Rt=Lt.	AP direct	mid.			
1. Appositional 2. AP-PA-Rt & Lt Lat. 3. Three Field 4. Box			5. SAD/SSD 6. Rotation 7. Wedge 8. Tangential			COMMENTS:
Depths	mid.	3 cms.				

X Simulation O Clinical X Individual Blocking O Cast O Bolus O Contour O Computer Plan O Split Course
O Re-evaluation O Spinal Cord ____ O Rest

Weekly CBC.

Date 6-27-88

Radiation Oncologist [signature]

PAGE 1

Attachment A4

APR 20 '89 15:18 FROM OPD CLINIC PAGE.003

Krest, Geraldine

TUMOR DOSE

NUMBER	SITE	1	Rt H+N	2	Lt H+N
SSD. SAD	ENERGY	80	125 MeV	80	125 MeV
FIELD SIZE	JAW SETTING	8.5x9.5	9x10	8.5 x 9.5	9x10
GANTRY ANGLE	HEAD ROTATION	270	0	90	0
COUCH ROTATION		—		—	
BLOCKS	COMPENSATOR	Yes	No	Yes	No
NSD (rets)					
TRUE AREA	EQUIV. SQ.				
WEDGE No.	WEDGE FACTOR	—	—	—	—
TAR	% DEPTH DOSE		78		78
MONITOR UNITS	TIME	2.03		2.03	
1988	DEPTH	5cm		5cm	

PROGRESS NOTES

Wt (kgs)	Hb/Hct	WBC	PLTS.
5-30 - 12.5/39.9 - 7.3 - 242,000			
29 - 136/386 - 5.9 - 323,000			
9.9 - 13.2/39.3 - 8.4 - 292,000			
7.13 - 12.3/36.5 - 4.7 - 294,000			
9.30 - 12.7/36.3 - 6.1 - 251,000			
8-3 - 12.5/36.5 - 8.5 - 239,000			

FX.	DATE	DATS	SIGN.	MU/Time	D MAX	TUMOR DOSE	MU/Time	D MAX	TUMOR DOSE	
1	6-28	1	gp	2.03	128	100	2.03	128	100	52
2	6-29	2	gp	2.03	129	100	2.03	129	100	400	53
3	6-30	3	gp	2.03	129	100	2.03	129	100	600	54
4	7-1	4	gp	2.03	129	100	2.03	129	100	800	55
							Treatment Stopped				
5	7-5	8	gp	2.03	129	100	2.03	129	100	1000	56
6	7-6	9	gp	2.03	129	100	2.03	129	100	1200	57
7	7-7	10	gp	2.03	129	100	2.03	129	100	1400	58
8	7-8	11	gp	2.03	129	100	2.03	129	100	1600	59
9	7-11	14	gp	2.03	129	100	2.03	129	100	1800	60
10	7-12	15	gp	2.03	129	100	2.03	129	100	2000	61
11	7-13	16	gp	2.03	129	100	2.03	129	100	2200	62
12	7-14	17	gp	2.03	129	100	2.03	129	100	2400	63
13	7-15	18	gp	2.03	129	100	2.03	129	100	2600	64
14	7-18	21	gp	2.03	129	100	2.03	129	100	2800	65
15	7-19	22	gp	2.03	129	100	2.03	129	100	3000	66
16	7-20	23	gp	2.03	129	100	2.03	129	100	3200	67
17	7-21	24	gp	2.03	129	100	2.03	129	100	3400	68
18	7-21	25	gp	2.03	129	100	2.03	129	100	3600	69
19	8-1	35	gp	2.03	129	100	2.03	129	100	3800	70
20	8-2	36	gp	2.03	129	100	2.03	129	100	4000	71
21	8-3	37	gp	2.03	129	100	2.03	129	100	4200	72
22	8-4	38	gp	2.03	129	100	2.03	129	100	4400	73
23	8-5	39	gp	2.03	129	100	2.03	129	100	4600	74
24	8-8	42	gp	2.03	129	100	2.03	129	100	4800	75
25	8-9	43	gp	2.03	129	100	2.03	129	100	5000	76

AGE 4 CHART CHECK LIST ✓ CONSENT O PATH REPORT ✓ PORT FILMS ✓ PHOTO

Attachment A5

3	AP Sagittal
80	125 mev
195.57	20x8
0°	0°
—	
Yes	No
—	—
	87.3
3.58	
30 cm	

MU/Time	D MAX	TUMOR DOSE		MU/Time	D MAX	TUMOR DOSE
3.58	229	200		6/28/88		
3.58	229	200	400			
3.58	229	200	600			
3.58	229	200	800	7/6/88		
3.58	229	200	1000			
3.58	229	200	1200			
3.58	229	200	1400			
3.58	229	200	1600	7/28/88		
3.58	229	200	1800			
3.58	229	200	2000			
3.58	229	200	2200			
3.58	229	200	2400			
3.58	228	200	2600	8/15/88		
3.58	228	200	2800			
3.58	228	200	3000			
3.58	228	200	3200			
3.58	228	200	3400			
3.58	228	200	3600			
3.58	228	200	3800			
3.58	228	200	4000			
3.58	228	200	4200			
3.58	228	200	4400			
3.58	228	200	4600	8/5/88		
3.58	228	200	4800			
3.58	229	200	5000	8/17/88		

8-3-88 cord. block

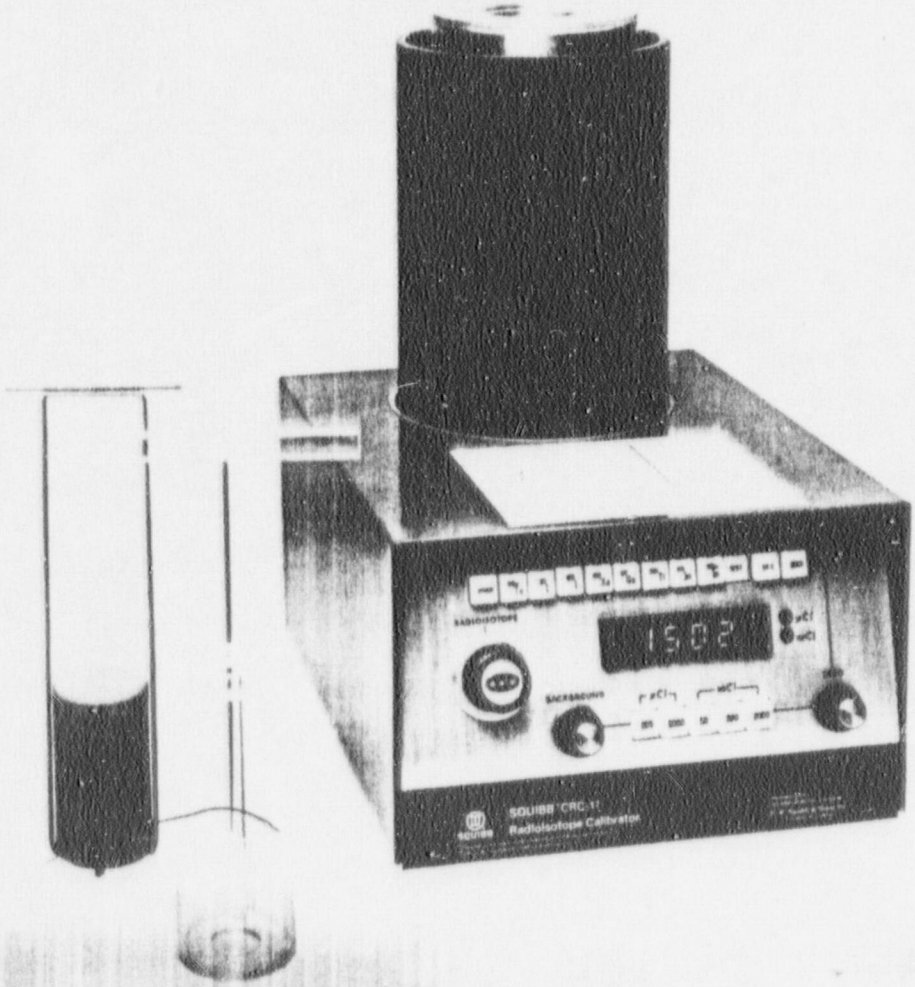
Technical Notes

1 7/28/88: Started
2 with 0.5 tx
3
4
5
6
7
8
9
10 7/6 4000 pt to dr
11
12
13
14 7/28/88 Tx to
15 dental device
16
17
18
19 7/28/88 at 3 to
20 next tech.
21
22
23 8/25/88: Retain
24 8/1/88
25
26
27
28 8/24/88: Tx ok
29 summary signed
30
31
32
33
34
35
36
37
38
39
40
41
42

TOTO ☒ DIAGRAMS ○ CHIEF TECH ○ PHYSICIST ○ PHYSICIAN

Attachment B,

SQUIBB CRC®-17 RADIOISOTOPE DOSE CALIBRATOR Operation Manual



Manufactured for

E. R. Squibb & Sons, Inc.

Princeton, New Jersey 08540
by Capintec, Inc.

For technical assistance:

ROT X 15

Milletron, Inc., a subsidiary of Capintec,
540 Alpha Drive, Pittsburgh, PA 15238.
~~Telephone: 412-781-5300~~
412 - 963 1988

* CRC is a registered tradename of Capintec, Inc.

Attachment B2

which is supplied with the instrument. Be sure to place the sample in the center axis of the chamber when measurements are made without the dipper or when measurements of extremely high activity are anticipated.

CAUTION

Refer to Sections 3.3 and 3.4 for details concerning accuracy of measurement.

5.3.3 MO ASSAY PROCEDURE

Procedure to assay a low level contamination of Molybdenum Mo 99 in solution of Technetium Tc 99m and the characteristics of the assay canister are described in this section.

Description

The Assay Kit consists of a lead canister of the proper dimension to accept a 30 milliliter vial, and an insertion holder. The characteristics of the canister are such that the ^{99m}Tc reading is reduced to less than 10^{-6} of the unshielded reading while the ^{99}Mo reading is reduced by approximately 65%.

The allowable level of ^{99}Mo contamination in technetium Tc 99m is generally considered to be one part per thousand at the time of injection. The procedure is carried out by simply taking two readings on the day's elution of ^{99m}Tc, one shielded and one unshielded. If the shielded reading ×3.5 (or × 5, see procedure 4 below) is not lower than the unshielded reading by a factor of 10^3, the required purity does not exist.

Assay Procedure

1) Push 200μCi Range button.

2) Be sure there are no radioisotopes near the calibrator. Push OTHER and set the calibration knob dial to 030 (or 080).
Since 080 is also the calibration number for ^{99m}Tc, the ^{99m}Tc push button may be selected at this point and left in position for the entire assay procedure.

3) Place the Mo Assay Canister gently into the chamber well (without the sample in it). Read and record the background, B.

4) Insert the elution vial into the Mo Assay Canister and take reading of Mo component, M.

5) Subtract the background from the reading with the sample in the canister, then multiply the number by 3.5 (or multiply the number by 5, if calibration knob is set to 080) to obtain contamination of ^{99}Mo in the ^{99m}Tc vial.
Activity of ^{99}Mo = 3.5 (M-B); @ cal setting 030
or
Activity of ^{99}Mo = 5.0 (M-B); @ cal setting 080

6) Push ^{99m}Tc push button or push OTHER and set the calibration knob dial to 080. Take out the sample vial from the Mo Assay Canister. Select appropriate Activity Range for ^{99m}Tc sample. Insert the vial into the ionization chamber well by using the plastic dipper (without any shield around the vial). Record the activity of ^{99m}Tc.

The contamination of ^{99}Mo in ^{99m}Tc must be less than 0.1%. It is considered to be a good practice to work with solutions having less than one part of ^{99}Mo contamination in 10,000 parts of ^{99m}Tc.

EXAMPLE

Measurement	Calibration Setting	Meter Reading	Activity
Background (with the Assay Canister in Well)	030 (080)	−00.2μCi (−00.1μCi)	
Mo 99 Contamination in Tc 99m	030	+02.4μCi	2.4 − (−0.2) = 2.6 2.6μCi × 3.5 = 9.1μCi*
(Tc 99m Vial in the Assay Canister)	(080)	(+1.7μCi)	(1.7 − (−0.1) = 1.8 1.8μCi × 5 = 9.μCi)
Tc 99m (No Vial Shield)	080	100.0mCi	100mCi

$$\text{Mo 99 Contamination} = \frac{\text{Mo 99 Activity}}{\text{Tc 99m Activity}} = \frac{9.1\mu\text{Ci}}{100\text{mCi}} = 0.9 \times 10^{-4}$$

*Leakage radiation from ^{99m}Tc is reduced to less than 0.0001% of the original value when the ^{99m}Tc vial is inserted into the Mo Assay Canister. The effect from the leakage radiation on the Mo assay measurement is up to 0.0005% of the ^{99m}Tc activity, e.g., effect from 100mCi ^{99m}Tc on the ^{99}Mo contamination measurement will be less than 0.5μCi.

CONFIRMATORY ACTION LETTER CAL-RIII-89-011

Attachment C

APR 14 1989

Ellis Fischel State Cancer Center
ATTN: Ronald Vincent, M.D.
115 Business Loop, 70 West
Columbia, MO 65203

License No. 24-00481-04

Gentlemen:

This refers to the telephone conversation between you and D. J. Sreniawski of this office on April 13, 1989 regarding your Picker 6096A cobalt-60 teletherapy unit which remained partially in the "beam on" position for approximately 10 minutes on April 4, 1989 during our inspection at your facility. The source subsequently retracted into the shielded "beam off" position.

Based on that conversation, it is our understanding that you will not use the Picker 6096A unit for any purpose until you:

1. Complete repair efforts on the teletherapy unit. (We understand this repair is being conducted by an appropriately licensed service contractor.)

2. Calibrate the unit following repairs in accordance with requirements in 10 CFR 35.632. This calibration will be performed by a physicist qualified in accordance with 10 CFR 35.961, who is also authorized as a teletherapy physicist on your license.

3. Notify this office when the teletherapy unit has been repaired and calibrated.

Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order requiring implementation of the above commitments. If your understanding differs from that set forth above, please call this office by telephone (312) 790-5500.

Sincerely,

Original signed by
A. Bert Davis

A. Bert Davis
Regional Administrator

cc: Denise Noonan, Ph.D.
DCD/DCB (RIDS)

bcc: J. Clifford, EDO
J. Lieberman, OE
L. Chandler, OGC
R. Bernero, NMSS
J. Austin, NMSS

RIII	RIII	RIII	RIII	RIII	RIII
Casey/jl	Sreniawski	Mallett	Grobe	Norelius	Davis
4-14-89	4/14	4/14	4/14	4/14/89	4/14

8904250088 (1p)