October 14, 2010

Arthur Rose, M.D.
Radiation Safety Officer
Franklin Medical Consultants
Farmbrook Medical Building I
29829 Telegraph Road
Suite A
Southfield, MI 48034

SUBJECT: NRC INSPECTION REPORT NO. 030-02121/2010-001(DNMS) — FRANKLIN MEDICAL CONSULTANTS

Dear Dr. Rose:

On August 26-27, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at Franklin Medical Consultants. Our inspection included an in-office review of the additional information you provided and your proposed corrective actions to the inspection findings. The inspection findings were discussed with you, at the conclusion of the inspection on September 17, 2010. The enclosed report presents the results of the inspection.

The inspection examined activities conducted under your NRC license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of your portable gauge activities in progress, independent measurements, and interviews with personnel.

Several unresolved items were identified during this inspection regarding your radiation safety program. The unresolved items involve: (1) an individual's failure to wear assigned extremity monitoring devices as required by License Condition 15.A; (2) the failure to perform surveys at the end of each day of use as required by License Condition 15.A; (3) the failure to perform surveys for removable contamination each week as required by License Condition 15.A.; (4) the process of performing surveys of incoming packages containing radioactive material as required by Title 10 of the Code of Federal Regulations (10 CFR) Part 20.1906; and (5) the failure to perform daily constancy tests on the dose calibrator as required by License Condition 15.A.

However, because these unresolved items remain under NRC review, no response for this letter is required at this time. You will be notified in separate correspondence of the results of our review. In addition, please be advised that the number and characterization of the unresolved issues described in the enclosed inspection report may change as a result of further NRC review.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions, please contact Ms. Deborah Piskura of my staff at 630-829-9867.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Division of Nuclear Materials Safety

Docket No. 030-02121
License No. 21-12460-01

Enclosure:
Inspection Report 030-02121/2010-001

cc w/encl: State of Michigan

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REGION III

Docket No.	030-02121
License No.	21-26408-01
Report:	030-02121/10-01(DNMS)
Licensee:	Franklin Medical Consultants
Location Inspected:	Farmbrook Medical Building I 29829 Telegraph Road Suite A Southfield, Michigan
Dates:	August 26-27, 2010
Final Exit Meeting:	September 17, 2010
Inspector:	Deborah A. Piskura, Health Physicist
Approved by:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Franklin Medical Consultants
Southfield, Michigan
NRC Inspection Report No. 030-02121/10-01(DNMS)

This was a routine inspection conducted on August 26-27, 2010, with continued in-office review through September 17, 2010. The purpose of the inspection was to evaluate the licensee's performance and compliance with the U.S. Nuclear Regulatory Commission (NRC) regulations and license conditions. The inspector reviewed several program areas including dose calibrator quality assurance tests, security, radiation protection, surveys, posting and labeling, and training.

During the inspection, several unresolved items were identified. These unresolved items will continue to be reviewed by NRC. The unresolved items included:

- an individual's failure to wear assigned extremity monitoring devices as required by License Condition 15.A;

- the licensee's failure to perform surveys at the end of each day of use as required by License Condition 15.A;

- the licensee's failure to perform surveys for removable contamination each week as required by License Condition 15.A;

- the licensee's processes for performing surveys (of incoming packages containing radioactive material as required by Title 10 of the Code of Federal Regulations Part 20.1906; and

- the licensee's failure to perform daily constancy tests on the dose calibrator as required by License Condition 15.A.

The licensee implemented immediate corrective actions to address the unresolved items. The licensee hired another technologist for the nuclear medicine department. The Radiation Safety Officer (RSO) committed to review all monthly reports generated by the dose management computer. The RSO also requested the consulting physicist to conduct more frequent reviews of the radiation safety program.

Report Details

1 Program Scope and Inspection History

Franklin Medical Consultants (licensee) is a multi-specialty private group practice employing 50 individuals. The licensee is authorized to use licensed material permitted by Title 10 of the Code of Federal Regulations (10 CFR) Sections 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma). The nuclear medicine department was staffed with one nuclear medicine technologist who performed approximately 80-100 diagnostic procedures monthly. Typically, in a year, the clinic administered 2 - 5 iodine-131 dosages for treatment of hyperthyroidism and Graves disease. The licensee received unit doses, bulk vials of technicium-99m for kit preparation, and iodine-131 capsules from a licensed radiopharmacy. Two physicians were listed as authorized users. The clinic experienced a decrease in its patient studies due to the shortage of molybedum-99 and local economic factors; the clinic performed nuclear medicine studies on Mondays, Tuesdays, Thursdays, and Fridays. The clinic retained the services of a consulting physicist who audited the radiation safety program on a quarterly basis.

The NRC previously inspected the licensee's activities on February 23, 2004, and February 14, 2007, with no violations noted.

2 Management Oversight

2.1 Inspection Scope

The inspector reviewed the licensee's management of the radiation safety program and the radiation protection program reviews. The inspector interviewed the office manager, the consultant physicist, and the RSO. The inspector also reviewed selected audit reports for the 2008 to the year-to-date 2010 period.

2.2 Observations and Findings

Dr. Arthur Rose served as the primary authorized physician user and the licensee's RSO. Dr. Rose also served as the president for the medical practice. The RSO is responsible for implementing the entire radiation safety program. The RSO was physically present at the clinic while nuclear medicine studies were performed. He reviewed and signed quarterly reports associated with the radiation safety program.

The licensee utilized a computerized dose management system to maintain the radiation safety recordkeeping. During the entrance meeting, the technologist informed the inspector that all the recent records (approximately 2008 to present) and the dose management computer was located at his residence because he was organizing the records and updating the computer inputs in anticipation of the NRC inspection. The inspector advised the technologist and the licensee management that records should be available for the inspector's review at the time of the inspection. The licensee management committed to make the records available to inspection on the following day. The nuclear medicine technologist stated that he transported the laptop computer to his residence to enter data into the computer during off-hours because he did not have time to enter the data while at the clinic. The technologist noted some daily tasks for August 26, 2010, (dose calibrator accuracy, package receipt surveys, and wipe and

area surveys) on the back of a patient requisition form. The inspector could only interpret the meaning of this data with the assistance of the technologist.

The licensee retained the services of a consulting physicist who audited the radiation safety program every calendar quarter. The consultant described how he attempted to conduct unannounced audits of the licensee's radiation safety program, on numerous occasions, but the technologist would request he wait for a later date due to the workload. The consultant typically arrived on-site unannounced as he preferred to conduct unannounced audits. The inspector's review of the consultant's audit reports found no description of these audit efforts; no violations or concerns were described in these reports. The RSO reviewed and signed the consultant's audit reports.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

3 Surveys

3.1 Inspection Scope

The inspector toured the nuclear medicine department. The inspector interviewed selected staff and observed area ambient radiation surveys and wipe surveys for removable contamination to evaluate the licensee's performance. The inspector reviewed records of area ambient radiation surveys and weekly wipe surveys maintained in the dose management computer between February and August 2010.

3.2 Observations and Findings

The inspector observed demonstrations of daily ambient surveys. The technologist also demonstrated how he surveyed the surfaces with the GM probe (held 6+ inches from the surface). The inspector asked about the action levels (when the area was considered contaminated or elevated/abnormal radiation readings) and the technologist responded "100 milliRoentgen per hour," which was not a typical action level compared to the most common action level of 2 milliRoentgen per hour in a hot lab or background in other imaging areas.

The inspector performed independent surveys of the hot lab, treadmill area and imaging areas and identified several areas with elevated radiation readings (greater than 5 milliRoentgen per hour), on the floor by the treadmill and the hot lab bench tops, indicating a presence of excessive contamination. The inspector noted that a sharps container read approximately 10 milliRoentgen per hour, indicating that radioactive waste had been mixed with non-radioactive (normal) biohazard waste. The inspector also alerted the technologist that a contaminated glove had been placed on top a trashcan containing non-radioactive waste.

Areas of contamination were identified in the hot lab and the treadmill area, with the highest readings on the hot lab counter (18,000 disintegrations per minute) and the hot lab floor (13,000 disintegrations per minute). According to the technologist's notes, the wipe results for these areas performed the same day were recorded as 222 disintegrations per minute and 126 disintegrations per minute respectively. The

inspector inquired about the licensee's action level and the technologist initially could not respond to the question. The inspector also observed the technologist attempt to decontaminate the treadmill room floor and noted that the technologist poured cleaning solution on the area and wiped the liquid over several floor tiles, essentially spreading the contamination over a larger area.

The inspector also performed independent surveys of unrestricted areas within the clinic and did not identify any contamination. The inspector also surveyed her shoes and the technologist's shoes which also did not identify any contamination.

The inspector identified that the licensee's records indicated that ambient exposure rate surveys were performed on dates where the clinic management confirmed that the office was not open for business (Memorial Day and Independence Day holidays, and on Saturday, July 17, 2010). In addition, surveys were indicated to be performed on several Wednesdays (between April 14, 2010, and July 28, 2010), where the clinic did not perform nuclear medicine studies. According to the licensee's records, no daily surveys were performed on July 9, 26, 27, 29, and 30, 2010, days when licensed material was received and administered to patients. In addition, according to the licensee's records reviewed as of August 27, 2010, no daily ambient exposure rate surveys were performed between August 2 and 25, 2010.

License Condition 15.A. (tie down) requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated November 19, 2004. Item 10, "Radiation Protection Program," of the application, dated November 19, 2004, states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. "Ambient Dose Rate Surveys" of the licensee's procedure Model Procedure for Area Surveys Model Procedures requires, in part, in radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter.

The failure to perform ambient surveys each day of use as required by License Condition 15.A. is an unresolved item. The circumstances surrounding the unresolved item continue to be under NRC review.

The inspector's review of the licensee records for the weekly area contamination surveys showed several inconsistencies in the time that the survey was performed. Further, according to the licensee's records, required weekly area contamination survey were not performed on several occasions for the weeks ending April 9 and 30, 2010, and August 6, 13, and 20, 2010.

License Condition 15.A. (tie down) requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated November 19, 2004. Item 10, "Radiation Protection Program," of the application, dated November 19, 2004, states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70. "Removable Contamination Surveys" of the licensee's procedure Model Procedure for Area Surveys Model Procedures requires, in part, in radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination.

The failure to perform weekly area contamination surveys as required by License Condition 15.A. is an unresolved item. The circumstances surrounding the unresolved item continue to be under NRC review

3.3 Conclusions

The inspector identified two unresolved items involving the failures to perform ambient surveys each day of use and weekly area contamination surveys as required by License Condition 15.A. These matters are considered unresolved items. The NRC will continue its review of these unresolved items.

4 Dose Calibrator

4.1 Inspection Scope

The inspector reviewed records of dose calibrator quality assurance tests maintained in the licensee's the dose management computer between February and August 2010. The inspector also interviewed the RSO and selected licensee staff.

4.2 Observations and Findings

Dose calibrator linearity checks and tests for accuracy were performed by the licensee's consultant during his quarterly audits.

According to the licensee's records, no daily constancy checks were performed on July 9, 26, 27, 29, and 30, 2010, days when licensed material was received and administered to patients.

License Condition 15.A. (tie down) requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated November 19, 2004. Item 9, "Dose Calibrator and Other Dosage Measuring Equipment" of the application, dated November 19, 2004, states that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. Number 1.a, of Item 9.3, entitled, "Model Procedure for Calibrating Dose Calibrator Model Procedure" requires, in part, to test the dose calibrator constancy at least once each day prior to assay of patient dosages.

The licensee's failure to perform daily dose calibrator constancy checks as required by License Condition 15.A. is an unresolved item. The circumstances surrounding this unresolved item continue to be under NRC review.

4.3 Conclusions

The inspector identified one unresolved item regarding the licensee's failure to perform daily constancy checks on the dose calibrator unit as required by License Condition 15.A. The NRC will continue its review of this unresolved item.

5 Personnel Monitoring

5.1 Inspection Scope

The inspector interviewed the RSO, and selected licensee personnel and reviewed select records and the personnel exposure reports from the dosimetry vendor.

5.2 Observations and Findings

The licensee provided whole body and extremity dosimetry to its personnel working in the nuclear medicine department. The dosimetry was exchanged every calendar quarter.

On August 26, 2010, the inspector noted that the technologist was not wearing his assigned extremity dosimeter. The inspector inquired about the dosimeter and was informed that is was in the technologist's car. Based on the patient schedule, the technologist failed to wear his assigned extremity dosimeter while he prepared assayed, and injected nine unit dosages of radiopharmaceuticals to five patients.

A review of the dosimetry reports for 2007 to YTD 2010, showed a steady decline in the extremity dosimetry readings, which were atypical for the technologist's workload. When the inspector returned on August 27, she noted that the technologist was wearing his extremity badge. The annual exposures (in millirem) were recorded as follows:

2007	2008	2009	Year-to-date 2010
159	490	357	187
886	297	174	40*

*This exposure represented for the first monitoring quarter of 2010 only.

The inspector inquired about the remaining extremity exposure data for the second quarter monitoring period. The technologist replied that the dosimetry vender must have lost his ring badge. It was subsequently identified that it was sent in late.

License Condition 15.A. requires the licensee to conduct its program in accordance with the statements, representations, and procedures in its Application dated November 19, 2004. Item 10, "Radiation Protection Program" of the application, states that the licensee has developed and will implement written procedures for safe use of unsealed byproduct material that will meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301. Number 8, of Item 10.4, "Model Rules for the Safe Use of Radiopharmaceuticals Model Rules," requires, in part, to wear a finger extremity monitor during the preparation, assay, and injection of radiopharmaceuticals.

The licensee's failure to wear a finger extremity monitor during the preparation, assay, and injection of radiopharmaceuticals as required by License Condition 15.A. is an unresolved item. The circumstances surrounding this unresolved item continue to be under NRC review.

5.3 Conclusions

The inspector identified one unresolved item regarding the licensee's failure to perform daily constancy checks on the dose calibrator unit as required by License Condition 15.A. The NRC will continue its review of this unresolved item.

6 Receipt of Packages Containing Radioactive Material

6.1 Inspection Scope

The inspector interviewed the RSO and selected licensee personnel. The inspector reviewed records of "Incoming DOT Wipe/Survey Listing" maintained in the licensee's the dose management computer between February and August 2010.

6.2 Observations and Findings

The inspector's review of the licensee's records for the package receipt showed several inconsistencies. The inspector identified an entry for receipt of licensed material on Saturday July 17, with a calibration date of July 22, 2010. For example, the records did not accurately describe the package contents because only one package can contain a maximum of eight unit doses. A review of the package receipts and package survey readings indicated that the package contained more than eight dosages received in one package. Further, according to the radiopharmacy, if a package contained a therapeutic quantity of I-131, that dosage would be shipped in a separate package and labeled as a "Yellow II" package. According to the licensee's records, the dosages appear to be received in one package and the survey readings did not appear to accurately reflect the expected readings. The inspector also noted that all package surveys for removable contamination always indicated "0 disintegrations per minute." In addition, all packages were received at the same time of day "8:00 a.m."

Title 10 CFR 20.1906 requires the licensee to monitor the external surfaces packages labeled with a Radioactive White I or Yellow II label for: (1) radioactive contamination, and (2) radiation levels. The licensee's process to monitor packages is an unresolved item. The circumstances surrounding this unresolved item continue to be under NRC review

6.3 Conclusions

The inspector identified one unresolved item regarding the licensee's performance of surveys of incoming packages containing radioactive material as required by 10 CFR 20.1906. The NRC will continue its review of this unresolved item.

7 Other Areas Inspected

7.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program, which included security of licensed material, training, use of therapeutic iodine-131, physical inventory and leak testing of sealed sources, labeling of containers, and postings. The inspector interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers, and reviewed selected records.

7.2 Observations and Findings

The inspector observed that the licensee personnel maintained constant surveillance of its licensed material. In addition, the nuclear medicine hot lab remained secured.

The inspector determined that the consultant provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.

The inspector reviewed written directives for three iodine-131 patient treatments. The licensee documented the written directive, the verification of the patient identity, and dosage verification. No medical events were identified.

The inspector examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the rooms where licensed material was used and stored were properly posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The hot lab was also posted with emergency/decontamination procedures and an approved "dosage chart."

7.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

8 Exit Meeting Summary

The inspector discussed the preliminary conclusions with licensee management during the exit meeting conducted at the licensee's facilities on August 27, 2010, and during a September 17, 2010, teleconference. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

Franklin Medical Consultants
*Tina Buczkowski , Office Manager
*Arthur Rose, M.D., RSO, Authorized User
Jack Zeller, RT(R), Nuclear Medicine Technologist

Radiological Physics Service, Inc.
Ray Carlson, M.S., President, Consulting Physicist
* Individuals present at exit meeting