October 21, 2011

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. 030-02121/10-001(DNMS), NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2011-001, AND NOTICE OF VIOLATION – FRANKLIN MEDICAL CONSULTANTS

Dear Dr. Rose:

On August 26 and 27, 2010, the U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the Franklin Medical Consultants. Five unresolved items were identified during this inspection regarding your radiation safety program as documented in the subject inspection report dated October 14, 2010. On September 27, 2011, we discussed the outcome of our deliberation regarding the unresolved items in detail with you via telephone.

On October 4, 2010, the NRC Office of Investigations (OI) initiated an investigation to determine if your former technologist willfully failed to wear his assigned extremity dosimetry; willfully failed to perform daily ambient radiation exposure rate surveys and willfully provided inaccurate and incomplete records of daily exposure rate surveys; willfully failed to perform package receipt surveys and willfully provided inaccurate and incomplete records of package receipt surveys; willfully failed to perform weekly area contamination surveys; and willfully failed to perform daily dose calibrator constancy checks. As a result of the investigation, the NRC did not find evidence that the technologist willfully failed to perform the actions described above; however, the technologist's actions resulted in violations of NRC requirements. A copy of the OI Report Synopsis is enclosed.

Based on the results of the inspection and investigation, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations involved: (1) an individual's failure to wear assigned extremity monitoring devices as required by License Condition 15.A; (2) the failure to maintain complete and accurate records for end of the day surveys, and weekly removable contamination surveys in accordance with Title 10 of the Code of Federal Regulations (CFR) 30.9(a); and (3) the failure to maintain complete and accurate records for dose calibrator constancy tests in accordance with 10 CFR 30.9(a).

The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited because the NRC inspector identified them.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in Information Notice 96-28, "Suggested Guidance Related to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In your response, please provide a description of the actions you have taken or plan to take in order to ensure the validity and accuracy of your records.

In addition, we are concerned with oversight of the radiation safety program in your role as the Radiation Safety Officer. During the inspection, we identified a number of performance issues concerning the manner in which surveys were conducted, your staff's understanding of survey trigger levels and contamination control, expectations to wear assigned dosimetry at all times while working with licensed material, and the maintenance of NRC required records. Your consulting physicist failed to identify these issues during his quarterly program audits. Although your consultant expressed concern regarding his inability to conduct unannounced audits, an individual's practice of not wearing his dosimetry, and the maintenance of NRC required records in your dose management computer; these concerns were not described in his audit reports.

Effective management of the radiation safety program is vital to licensees achieving safe and compliant operations. During your transcribed interview with OI investigator, you acknowledged that you were not paying close attention to the program. Two of the violations involved records required to be maintained by the licensee that were not complete and accurate in all material respects. The NRC inspection process relies upon licensees maintaining complete and accurate records. Therefore, any licensee action that could affect our confidence in the veracity of information is of concern. In addition to providing a response for each of the items listed in the Notice, please also discuss how you intend to improve your oversight of the radiation safety program.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be 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. To the extent possible, your response should not include any personal privacy, propriety, or safeguards information so that it can be made available to the public without redaction. You should note that final NRC documents, including the final OI reports, may be made available to the public under the Freedom of Information Act (FOIA) subject to redaction of information pursuant to the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, Request for Records. The instructions for making a request for information under the FOIA are accessible at http://www.nrc.gov/reading-rm/foia/foia-request.html.

If you have any questions regarding this matter, please contact Tamara Bloomer at (630) 829-9627.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials and Safety

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

Enclosures:
1. Notice of Violation
2. OI Report Synopsis

cc w/encls: State of Michigan

If you have any questions regarding this matter, please contact Tamara Bloomer at (630) 829-9627.

Sincerely,

/RA/

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cc w/encls: State of Michigan

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NOTICE OF VIOLATION

Franklin Medical Consultants
Southfield, Michigan

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 26 and 27, 2010, and an investigation conducted by the NRC Office of Investigations, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. License Condition 15.A. requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an 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 Title 10 of the Code of Federal Regulations (CFR) 20.1101 and 10 CFR 20.1301.

Paragraph 8, of Item 10.4, "Model Rules for the Safe Use of Radiopharmaceuticals Model Rules," states, in part, "wear a finger exposure monitor during the preparation, assay, and injection of radiopharmaceuticals."

Contrary to the above, on August 26, 2010, a nuclear medicine technologist failed to wear his assigned finger exposure monitor while he prepared, assayed, and injected nine unit dosages of radiopharmacueticals for five patients.

This is a Severity Level IV Violation (Section 6.3).

B. Title 10 CFR 30.9(a) requires, in part, that information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material aspects.

License Condition 15.A. requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an 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.

Item 10.8, "Model Procedure for Area Surveys Model Procedures," requires, in part, that the licensee survey at the end of each day of use with a radiation detection survey meter, and survey weekly for removable contamination, in radiopharmaceutical elution, preparation, and administration areas and keep a record of dose rate and contamination survey results.

Contrary to the above,

1. The licensee failed to maintain records for end of the day surveys conducted in radiopharmaceutical elution, preparation, and administration areas, on April 23;

May 26; June 29; July 9, 26, 27, 29, and 30; and August 2 through 25, 2010. In addition, end of the day surveys were recorded for February 22; March 24; April 7, 14, 21 and 28; May 5, 7, 12, 14, 19, and 31 (holiday); June 4 and 9; and July 5 (holiday), 22, and 23, 2010, when the facility was either closed or did not perform nuclear medicine studies that day. Specifically, inconsistent and inaccurate documentation relative to the survey data was maintained, which limits the NRC's ability to confirm if surveys were performed as required.

2. The licensee failed to maintain records for weekly removable contamination surveys conducted in radiopharmaceutical elution, preparation, and administration areas for the weeks ending April 9 and 30; and August 6, 13, and 20, 2010.

This is a Severity Level IV Violation (Section 6.3).

C. Title 10 CFR 30.9(a) requires, in part, that information required by the Commission's regulations to be maintained by the licensee, shall be complete and accurate in all material aspects.

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 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. Paragraph 1.a, of Item 9.3, entitled, "Model Procedure for Calibrating Dose Calibrator Model Procedure," requires, in part, that the licensee test the dose calibrator constancy at least once each day prior to assay of patient dosages. Paragraph 3 of Item 9.3, requires in part, that the licensee either plot on graph paper or log the net activity of each constancy source, and repeat the above procedure for a commonly used radioisotope setting, and plot or log the results.

Contrary to the above, the licensee failed to maintain dose calibrator constancy test records (plots or logs) complete and accurate in all material respects. Specifically, the licensee maintained inconsistent and inaccurate records for dose calibrator constancy tests indicating that tests were conducted on the following days: June 29; July 26, 27, 30; and August 2 through 25, 2010. Additionally, tests were recorded for February 22; March 24; April 7, 14, 21, and 28; May 5, 7, 12, 14, 19, 26, and 31 (holiday); June 4, 9, 12, and 13 (weekend); and July 5 (holiday), 6, and 22, 2010, when the facility was either closed or did not perform nuclear medicine studies that day. This limits the NRC's ability to confirm if the tests were performed as required.

This is a Severity Level IV Violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Franklin Medical Consultants 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 III 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addressed the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 21st day of October 2011.

SYNOPSIS

This investigation was initiated on October 4, 2010, by the U.S. Nuclear Regulatory Commission, Office of Investigations, Region III, to determine if a Radiation Technologist at Franklin Medical Consultants (Franklin), Southfield, Michigan, willfully failed to wear his assigned extremity dosimetry badge (Concern 1); willfully failed to perform daily ambient radiation exposure rate surveys and willfully provided inaccurate and incomplete records of daily exposure rate surveys (Concern 2); willfully failed to perform package receipt surveys and willfully provided inaccurate and incomplete records of package receipt surveys(Concern 3); willfully failed to perform weekly area contamination surveys (Concern 4); and willfully failed to perform daily dose calibrator constancy checks (Concern 5).

Based upon the evidence developed, this investigation did not substantiate the allegations that the Radiation Technologist: willfully failed to wear his assigned extremity dosimetry badge (Concern 1); willfully failed to perform daily ambient radiation exposure rate surveys and willfully provided inaccurate and incomplete records of daily exposure rate surveys (Concern 2); willfully failed to perform package receipt surveys and willfully provided inaccurate and incomplete records of package receipt surveys (Concern 3); willfully failed to perform weekly area contamination surveys (Concern 4); and willfully failed to perform daily dose calibrator constancy checks (Concern 5).