December 19, 2012

Bradley D. Bastow, D.O.
Radiation Safety Officer
950 Blue Star Highway
Suite 1-2
South Haven, MI 49090

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03035710/2012001(DNMS) – BRADLEY D. BASTOW, D.O.

Dear Dr. Bastow:

On February 28, and April 3, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your facility, 950 Blue Star Highway, South Haven, Michigan, with continuing in office review through May 24, 2012. The in-office review included additional information provided by your contractor, University Nuclear Diagnosis, LLC, (UND), which was not available during the onsite inspections. A final exit meeting was held between Mr. Robert Hays of my staff and Phil Troy, Attorney, Jeff Prested, Nuclear Medicine Technologist, and you by telephone on November 28, 2012.

During this inspection the NRC staff 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 diagnostic nuclear medicine activities in progress, independent measurements, and interviews with personnel.

Based on the results of this inspection, the NRC has identified a number of open items for further review. The open items are described in the enclosed report. The NRC will continue to review these open items and you will be advised by separate correspondence of the results of our deliberations on these matters. No response to this letter is required at this time.

In accordance with Title 10 of the Code of Federal Regulations (CFR) Section 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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Mr. Bill Lin of my staff if you have any questions regarding this inspection. You can reach Mr. Lin at 630-829-9829.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-35710
License No. 21-32316-01

Enclosure:
Inspection Report 03035710/2012001

cc w/encl: State of Michigan
State of Florida

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REGION III

Docket No.	030-35710
License No.	21-32316-01
Report No.	03035710/2012001(DNMS)
Licensee:	Bradley D. Bastow, D. O.
Location Inspected:	950 Blue Star Highway Suite 1-2 South Haven, Michigan
Dates:	February 28, 2012 and April 3, 2012, with continuing review through May 24, 2012
Final Exit Meeting:	November 28, 2012
Inspectors:	Robert P. Hays, Health Physicist Bill C. Lin, Health Physicist Tamara E. Bloomer, Branch Chief
Approved by:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Bradley D. Bastow, D. O.
South Haven, Michigan
NRC Inspection Report No. 03035710/2012001(DNMS)

This was a special inspection conducted on February 28, 2012, and April 3, 2012, with continued in-office review through May 24, 2012. 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 inspectors reviewed several program areas including personnel dosimetry, dose calibrator linearity tests, Department of Transportation (DOT) requirements, radiation safety equipment as specified in the license applications, survey meter calibrations, efficiency tests of the survey meter, radiation protection, area surveys, training, leak tests and inventory of sealed sources, and ALARA reviews.

During the inspections, the inspectors identified a number of open items for further review. The open items are described in the enclosed report. The NRC will continue to review these open items and you will be advised by separate correspondence of the results of our deliberations on these matters.

Report Details

1 Program Scope and Inspection History

Bradley D. Bastow, D.O. (licensee) is a medical private practice authorized to use licensed material permitted by 10 CFR Sections 35.100 and 35.200. The majority of licensed activities involved rest and stress cardiac tests. The nuclear medicine department was staffed with one part-time nuclear medicine technologist who performed an average of 2-4 diagnostic procedures on Mondays and Tuesdays each week. The licensee received and used licensed material compounded as radiopharmaceutical unit doses of labeled technetium-99m from a licensed nuclear pharmacy. Dr. Bastow served as the authorized physician user and the licensee's Radiation Safety Officer (RSO). Dr. Bastow also was the owner of the medical practice. The RSO was physically present at the clinic while nuclear medicine studies were performed. The licensee had contracted with a nuclear medicine service provider, University Nuclear and Diagnostics, LLC, Davie, Florida, (UND) to provide nuclear medicine services for the licensee which included the nuclear medicine technologist (NMT) and other radiation safety program aspects as required by the NRC.

The NRC previously inspected the licensee's activities on October 25, 2010, and August 22, 2005, with no violations noted.

2 Personnel Monitoring

2.1 Inspection Scope

The inspector interviewed the NMT, the UND consultant, and reviewed select available personnel exposure reports.

2.2 Observations and Findings

During the inspection on February 28, 2012, the inspector observed that the NMT was wearing a personnel monitoring device (dosimeter). The inspector requested to see the NMT's dosimeter for a closer inspection and observed the dosimeter to have another individual's name on the dosimeter. The inspector asked the NMT why he was wearing a dosimeter that had been issued to another NMT. The NMT informed the inspector that he had been trying to get a dosimeter issued to him, but UND had not issued the NMT a dosimeter. The NMT informed the inspector that he had begun working at the licensee's facility on December 13, 2011, and had been handling and injecting patients with licensed material for a time period of approximately two and half months without being issued a dosimeter. During the inspection, the inspector was contacted by the UND consulting physicist to discuss the dosimeter issue. The UND consulting physicist agreed to order the dosimeters for the NMT. License Condition No. 15.A. of NRC License No. 21-32316-01 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the Application dated April 26, 2011, Item 9.4, Personnel Monitoring Program. Item 9.4(2) states, "All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body radiation exposure measuring device." Item 9.4(3) states, "All individuals who handle radioactive material on a regular basis will be issued a finger radiation exposure measuring device." The failure to issue the NMT a whole body film badge and a finger dosimeter from December 13, 2011, to March 5, 2012, is an open item under further NRC review.

In addition to the licensee's failure to issue a dosimeter to the NMT, the licensee is required by License Condition 15.B. in the facsimile dated October 21, 2011, under the section entitled, "Radiation Safety Program," and item 2, under the subsection, "Radiation Exposure Records," the licensee is required to read film badges on a monthly basis and the results evaluated by the RSO, and the RSO is required to keep permanent records of employee exposure. The inspector asked the UND consultant about dosimetry records that were not available on site at the licensee's facility. The UND physicist subsequently faxed the requested dosimetry records to the inspector on March 9, 2012, for review. The failure of the RSO to evaluate film badge results on a monthly basis, and to identify that the NMT had not been issued film badges is an open item under further NRC review.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, two open items were identified. The first open item involved the licensee's failure to issue film badges to the NMT from December 13, 2011, until March 5, 2012. After the licensee was notified by the inspector that the NMT had not been issued film badges, the licensee took corrective actions and provided film badges to the NMT. The NMT notified the inspector via email on March 5, 2012, that he had received the film badges. The second open item was identified by the inspector for the RSO's failure to evaluate film badge results on a monthly basis as required, which would have identified that the NMT had not been issued dosimetry.

3 Leak Tests and Sealed Source inventory

3.1 Inspection Scope

The inspector reviewed records of sealed source inventories and leak tests as required by 10 CFR 35.67(b)(2) and 10 CFR 35.67(g) for sealed sources used for testing of licensee instrumentation.

3.2 Observations and Findings

According to the licensee's records, leak tests were performed on the following dates: June 15, 2010, January 25, 2011; and March 05, 2012. One record dated August 8, 2011, indicates that leak tests were performed on March 5, 2012. The time period between each leak test indicates that leak tests were conducted at intervals greater than six months as required. The time period between June 15, 2010, and January 25, 2011, is 7 months and 10 days, the time period between January 25, 2011, and March 5, 2012, is 13 months and 9 days. Title10 CFR 35.67(b)(2), requires a licensee in possession of a sealed source, to test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission. The failure to leak test sealed sources at intervals not to exceed 6 months is an open item under further NRC review.

According to licensee's records, physical sealed source inventories were performed on June 15, 2010, August 5, 2011, and March 5, 2012. The time period between each physical sealed source inventory indicates that physical sealed source inventories were conducted at intervals greater than semi-annually as required. The time period between June 15, 2010, and July 20, 2011, is 12 months and 5 days, the time period between July 20, 2011, and March 5, 2012, is 7 months and 15 days. Title 10 CFR 35.67(g)

requires, in part, a licensee in possession of sealed sources shall conduct a semi-annual physical inventory of all such sources in its possession. The failure to conduct a semi-annual physical inventory is an open item under further NRC review.

3.3 Conclusions

Based upon a review of the licensee's leak tests and physical sealed source inventory records, an open item regarding 10 CFR 35.67(b)(2) was identified for the licensee's failure to leak test sealed sources as required and an open item regarding 10 CFR 35.67(g) was identified for a failure to conduct physical inventories semiannually.

4 Surveys

4.1 Inspection Scope

The inspector reviewed records of area ambient radiation surveys and weekly contamination surveys (wipe tests) as required by License Condition No. 15.A.

4.2 Observations and Findings

According to available licensee records, no daily surveys were performed on November 28, 2011, November 29, 2011, December 5, 2011, December 13, 2011, and December 14, 2011, days when licensed material was received and administered to patients. In addition, another licensee record indicates that the licensee's survey meter was not available and out for calibration somewhere in the State of Florida from October 5, 2011, to November 28, 2011.

License Condition 15.A. requires the licensee to conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011. Under Item 10.12, "Area Survey Procedures," Item 10.12(1) in the Application dated April 26, 2011, requires in part, that all areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed at the end of each day of use for ambient radiation exposure rates. Item 10.12(2) requires in part, that all areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates. The failure to survey all areas where radiopharmaceuticals are eluted, prepared, and administered at the end of each day of use for ambient radiation exposure rates and survey weekly areas where radioactive materials are stored is an open item under further NRC review.

Item 10.12(1) of the Application dated April 26, 2011, requires in part, that all areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed weekly for removable contamination. Item 10.12(2) of the Application dated April 26, 2011, requires in part, that all areas where radioactive materials are stored will be surveyed weekly for removable contamination. Item 10.12(4) in the Application dated April 26, 2011, requires in part, that surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 disintegrations per minute (dpm). The results will be recorded as net dpm per 100 square centimeters. A review of available licensee daily records dated from November 14, 2011, to December 14, 2011, indicated that no weekly contamination surveys were performed as required. The failure to survey weekly for removable contamination in all areas where

radiopharmaceuticals are eluted, prepared, administered, and stored is an open item under further NRC review.

In addition, during the time period, October 5, 2011 to November 28, 2011, that the licensee's survey meter was out for calibration, licensee daily records, indicated that ambient surveys were performed. As an example, on November 14, 2011, and November 21, 2011, licensee records indicate that area surveys were performed on those dates. The licensee's failure to have a survey meter available on those dates and records indicating that ambient surveys were performed is an open item under further NRC review.

4.3 Conclusions

Based upon a review of the licensee's records of daily use from November 14, 2011, to December 14, 2011, an open item regarding License Condition 15.A. was identified for a failure to perform ambient surveys at the end of each day of use and weekly for areas where radioactive materials are stored. Another open item regarding License Condition 15.A. was identified for the licensee's failure to perform weekly surveys for removable contamination in all areas where radiopharmaceuticals are eluted, prepared, administered, and stored. An additional, open item pertaining to licensee's failure to have a survey meter available on certain dates and daily records indicating that ambient surveys were performed. These open items are under further NRC review.

5 Survey Meter Calibrations and Efficiency test

5.1 Inspection Scope

The inspectors reviewed calibration records and efficiency tests used for determining if the survey meter's detectability was sensitive enough using a procedure to detect 2000 dpm to assay wipe tests.

5.2 Observations and Findings

The licensee had one survey meter, a Ludlum Model 14C, serial number 172810, and used a Model 44-9 pancake probe for performing surveys and wipe test counting. License Condition 15.A. requires the licensee to conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011. Under Item 9.2, "Calibration of Survey Instruments" in the Application dated April 26, 2011, requires, in part, that survey instruments will be calibrated by any authorized user licensed to perform survey meter calibrations. A review of two calibration records dated August 13, 2010 and November 10, 2011, indicated that the licensee's survey meter had been calibrated by the licensee's consultant, UND, under Florida Radioactive Materials License 4072-1. A review of calibration procedures (Appendix V) authorized under Florida License number 4072-1, indicated that survey meter calibration records shall include the certified dose rates from the source, the correction factors deduced from the calibration data, and the source is of sufficient strength to give an exposure rate of approximately 30 millirem/hour (mR/hr) at 100 cm (typical minimum activities are 85 mCi of Cs-137). The calibration records indicated that the calibration source used for the survey meter calibrations was a 206.9 microcurie Cesium (Cs) -137 source, assay date, March 1, 2008, and the calibration record did not include the certified dose rates from the source, nor the correction factors deduced from the calibration data. The failure to calibrate the licensee's survey meter in accordance with calibration

procedures as required by Appendix V, authorized by Florida Radioactive Materials License Number 4072-1, is an open item under further NRC review.

The inspectors reviewed the licensee's procedures for conducting weekly contamination surveys and contamination surveys (wipes) of DOT labeled packages containing radioactive material. The review determined that the licensee had possessed a well counter which was used to assay the wipes until the well counter failed to function. Rather than repairing the well counter after it had failed to function, the licensee began to assay wipes using the licensee's survey meter. License Condition 15.A. requires the licensee to conduct its program in accordance with the statements, representations, and procedures in the Application dated April 26, 2011. Under Item 10.12, "Area Survey Procedures," Item 10.12(4) in the Application dated April 26, 2011, requires in part, that surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm. The licensee's procedure to detect 2000 dpm using the survey meter was not available during the inspection, so the UND consultant provided a procedure via fax that the licensee followed for using a survey meter to analyze a wipe test. The procedure indicated that the survey meter had an efficiency of six percent for counting smears to detect Technetium (Tc) -99m; however, there was no indication of how the six percent efficiency was derived or a procedure that showed the survey meter to be sufficiently sensitive to detect 2000 dpm. The failure to use a procedure that is sufficiently sensitive to detect 2000 dpm on a series of wipes is an open item under further NRC review.

In addition, during the review of the survey meter calibration records, both calibration records were identical with the exception of the dates that each calibration was performed. The calibration data also suggests that a calibration source of 206.9 microcuries of Cs-137, with an assay date of March 1, 2008, can produce an exposure rate of 1300 mR/hr on the 1000x scale of the survey meter and the survey meter can detect the same exposure rate of 1300 mR/hr as the actual exposure rate, requires additional review and is an open item under further NRC review.

5.3 Conclusions

Based upon a review of the licensee's calibration records for August 13, 2010, and November 10, 2011, an open item regarding License Condition 15.A. was identified for the licensee's failure to calibrate the licensee's survey meter in accordance with calibration procedures required by Appendix V, authorized by Florida Radioactive Materials License Number 4072-1. Another open item regarding License Condition 15.A. was identified for the licensee's failure to use a procedure that is sufficiently sensitive to detect 2000 dpm on a series of wipes. An additional open item was identified pertaining to the licensee's calibration data which can produce an exposure rate of 1300 mR/hr on a calibration point of the survey meter and the survey meter can detect the same exposure rate of 1300 mR/hr as the actual exposure rate. These open items are under further NRC review.

6 Receipt of Packages Containing Radioactive Material and Instructions to Workers

6.1 Inspection Scope

The inspector reviewed licensee records of receipt, use, and disposal of licensed material as authorized by the license and the training of the NMT related to using procedures as required by License Condition 15.

6.2 Observations and Findings

The inspector's review of licensee records pertaining to receipt of packages determined that packages received November 14, 2011, November 21, 2011, November 28, 2011, November 29, 2011, December 5, 2011, and from December 13, 2011 through March 5, 2012, had not been wipe tested for contamination as required. Title 10 CFR 20.1906(b) requires in part, each licensee shall: (1) Monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, 49 CFR 172.403 and 172.436-440, for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; (3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged; and (c) the licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours. The failure to monitor the external surfaces of a labeled package for radioactive contamination is an open item under further NRC review.

The inspection determined that the NMT working at the time of the inspection, had begun working at the licensee's facility on December 13, 2011. An interview with the NMT determined that the NMT had been given some initial training by UND personnel pertaining to required duties, specifically, the use of radioactive material. The NMT was also questioned about why contamination surveys had not been performed from the NMT's start date of December 13, 2011, through February 28, 2012, the day of the inspection. The NMT indicated that he was not sure how to conduct contamination surveys since the well counter was not working. The inspection determined that there was no procedure available for performing contamination surveys and subsequently the UND consultant had provided the procedure via fax for performing contamination surveys using a survey meter. Title 10 CFR 19.12(a)(2) requires in part, all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 millirem (mrem) (1 mSv) shall be instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed. The failure of the licensee to provide the NMT with instructions on how to perform contamination surveys is an open item under further NRC review.

6.3 Conclusions

The inspectors identified an open item for the licensee's failure to monitor the external surfaces of a labeled package for radioactive contamination as required by 10 CFR 1906(b). An open item was also identified for the licensee's failure to provide the NMT with instructions on how to perform contamination surveys from December 13, 2011 until March 5, 2012, as required by 10 CFR 19.12(a)(2). These open items are under further NRC review.

7 Dose Calibrator

7.1 Inspection Scope

The inspectors reviewed records of required dose calibrator tests, which include daily constancy tests, quarterly linearity tests and annual accuracy tests. The review also included interviews of the licensee's consultant physicist.

7.2 Observations and Findings

A review of the available licensee's records indicated that constancy tests were performed on the dose calibrator using a calibration source containing Cs-137 on each day of use that patient studies were conducted. Licensee records also indicated that annual accuracy tests were performed on February 3, 2010, and January 25, 2011. The inspectors reviewed dose calibrator linearity records which indicated that linearity tests were performed quarterly on October 25, 2010, January 25, 2011, April 25, 2011, August 5, 2011, November 30, 2011, and March 5, 2012. A perusal of the linearity test records indicated that each linearity test had been performed using a Calicheck system. A Calicheck system is a nationally recognized standard and involves a series of tubular shields and when used according to the manufacturer's instructions, can shorten the linearity test time of the dose calibrator from days to minutes. Each tubular shield and a combination of tubular shields have a predetermined calibration factor that is used to determine if the dose calibrator is assaying radioactivity in a linear fashion. For each linearity test, the predetermined calibration factors are standard for that particular dose calibrator and do not change. The test requires an initial amount of radioactivity equivalent to the highest dose administered to a patient, and using the tubular shields and calibration factors in a prescribed order, the dose calibrator can be determined if it is functioning linearly. A review of the licensee's dose calibrator linearity test records did not provide the results indicating the dose calibrator was functioning linearly as required. In addition, the calibration factors used for determining linearity were not standardized and changed for each quarterly test. An interview with the consultant physicist determined that he did not have a record of the predetermined calibration factors for the Calicheck System and he was unable to explain how the calibration factors were calculated and why the calibration factors changed for each linearity test. As a result of the review of the linearity tests, the licensee's dose calibrator had not been properly tested for linearity from October 25, 2010, through March 5, 2012. Title 10 CFR 35.60(b) requires that a licensee shall calibrate the instrumentation required in paragraph 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. The failure to test the dose calibrator for linearity in accordance with nationally recognized standards is an open item under further NRC review.

The licensee's linearity test records indicate that the Calicheck system was used, although improperly. Subsequent correspondence by the consultant physicist's attorney informed NRC that the consultant physicist did not travel with a Calicheck System to the licensee's facility to perform linearity tests and the licensee did not have a Calicheck System available. The licensee's failure to have a Calicheck System available to perform linearity tests on those specified dates and records indicating that linearity tests were performed using a Calicheck System is an open item under further NRC review.

7.3 Conclusions

The inspectors identified an open item regarding 10 CFR 35.60(b) for a failure to test the dose calibrator for linearity in accordance with nationally recognized standards. One open item was identified pertaining to the licensee's use of a Calicheck System for testing the dose calibrator for linearity. These open items are under further NRC review

8 Radiation Safety Program Oversight

8.1 Inspection Scope

The inspectors reviewed the licensee's management and oversight of the radiation safety program and the radiation protection program reviews conducted by the licensee's contractor, UND. The inspectors interviewed the nuclear medicine technologist and contractor staff. The inspectors also reviewed selected records and reports for calendar years 2010, 2011, and to March 5, 2012.

8.2 Observations and Findings

The licensee's nuclear medicine studies were routinely conducted on Mondays and Tuesdays each week. The inspectors observed that the current nuclear medicine technologist and previous nuclear medicine technologists utilized a one-sheet paper record system for the required recordkeeping of receipt, use, and disposal of licensed material for each day that licensed material was used. The nuclear medicine technologist's radiation safety duties and procedures included, but not limited to, for each day of use, documenting a dose calibrator constancy test, documenting package surveys and wipe tests, documenting ambient area surveys, and documenting assays of unit doses prior to injection, on the paper record used by the NMT for recordkeeping each day licensed material is used or administered.

A review of an annual ALARA review indicated that the review was performed by the licensee's contractor, UND. The Application dated April 26, 2011, under Item 10.2, Management Commitment, Item 1.b. states in part, that all pertinent responsibilities will be met by the RSO and will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants. Item 3.a.(1) of the application dated April 26, 2011, also states in part, that the RSO will perform an annual review of the radiation safety program. A further review of the annual ALARA review details indicated that documents pertaining to receipt of radioactive materials and opening of packages containing radioactive materials were reviewed by the UND consultant and there were no recommendations. The information identified in the annual ALARA review is contradictory to what the inspector identified. As an example, the inspector's review of the most recent records pertaining to receipt of packages just prior to the ALARA review determined that packages received November 14, 21, 28, and 29, 2011, indicate the packages had not been wipe tested for contamination as required. The record dated November 28, 2011 also indicated that no survey meter or well counter were available and the ALARA review dated November 30, 2011, indicated no further action was taken by the UND consultant and the review stated there were no recommendations. Another example of the quality of the ALARA review states "That State of Florida Radioactive Materials License is current and reflective of operations and practices of nuclear medicine at this facility." The licensee has

a NRC license, not a State of Florida license. A copy of the review provided by the UND consultant was not signed by the RSO. Another audit dated March 5, 2012, indicated that dosimetry reports were in compliance, when on March 5, 2012; the NMT was issued a dosimeter that day and had not been issued a dosimeter from December 13, 2011, until March 5, 2012. The March 5, 2012, audit indicates that wipe tests were in compliance when no wipe tests had been performed from December 13, 2011, until March 5, 2012, when an open item was also identified for the licensee's failure to provide the NMT with instructions on how to perform contamination surveys from December 13, 2011 until March 5, 2012, as required by 10 CFR 19.12(a)(2). Because the audit did not identify that wipe tests had not been performed from December 13, 2011, until March 5, 2012, the quality of the annual ALARA audit results is a concern to the NRC. The failure of the RSO to conduct annual ALARA reviews is an open item under further NRC review.

In addition to the RSO's failure to evaluate film badge results on a monthly basis as required and the failure to conduct annual ALARA reviews, additional records required to be maintained by the licensee had to be obtained through the licensee's consultant, UND. The following records were either not available or were incomplete and not available for review during the inspections on February 28, 2012 and April 3, 2012: (1) Personnel Dosimetry; (2) Survey Meter Calibrations; (3) Dose calibrator linearity tests; (4) Dose calibrator accuracy tests; (5) Sealed Source inventory; (6) Leak tests for sealed sources; (7) ALARA audits; (8) training records for NMTs; (9) changes in radiation safety equipment such as the change from using a well counter to the use of the survey meter for wipe test counting; (10) summary reports for quarterly reviews of occupational exposures; and (11) summary reports of quarterly reviews of survey records.

The RSO is responsible for ensuring implementation of the entire radiation safety program, in compliance with federal regulations, and the application dated April 26, 2011, and a second application dated October 21, 2011, as a facsimile. Title 10 CFR 35.24(b) requires in part, a licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. The failure of the RSO to ensure that: (1) film badge results are evaluated on a monthly basis; (2) sealed sources are leak-tested at intervals not to exceed 6 months; (3) semi-annual physical inventories are performed; (4) all areas are surveyed where radiopharmaceuticals are eluted, prepared, and administered at the end of each day of use for ambient radiation exposure rates and weekly in areas where radioactive materials are stored; (5) all areas where radiopharmaceuticals are eluted, prepared, administered, and stored are surveyed weekly for removable contamination; (6) the licensee's survey meter is calibrated in accordance with calibration procedures as required by Appendix V, authorized by Florida Radioactive Materials License Number 4072-1; (7) a survey meter procedure is used that is sufficiently sensitive to detect 2000 dpm on a series of wipes; (8) the external surfaces of a labeled package are monitored for radioactive contamination upon receipt; (9) the NMT was given instructions on how to perform contamination surveys; (10) the dose calibrator is tested for linearity in accordance with nationally recognized standards; and (11) quality annual ALARA reviews are conducted, is an open item. The Annual ALARA review dated November 30, 2011, and is an open item. These open items are under further NRC.

8.3 Conclusions

The inspectors identified three open items: (1) regarding License Condition 15.A. for the failure of the RSO to conduct annual ALARA reviews; (2) regarding 10 CFR 35.24(b) for the RSO's failure to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements; and (3) regarding the licensee's ALARA review dated November 30, 2011, and are under further NRC review.

8 Exit Meeting Summary

The inspector discussed the preliminary conclusions with licensee's contractor, UND, during a meeting conducted at the contractor's facilities on May 24, 2012, and during a November 28, 2012, 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

Bradley D. Bastow, D.O.
*Brad Bastow, D.O., RSO, Authorized User
*Phil Troy, Attorney

University Nuclear Diagnostics, LLC
Armando Clavero, Consulting Physicist
*Jeff Prested, Nuclear Medicine Technologist

* Individuals present at exit meeting