February 13, 2014

EA-14-028

Mr. Eric Swank
Executive Director, Research Compliance
IUPUI/Indiana University Medical Center
Radiation Safety Office
541 Clinical Drive
Indianapolis, IN 46202-5111

SUBJECT: NRC ROUTINE INSPECTION REPORT NOS. 03001609/2014001(DNMS) AND 03009792/2014001(DNMS) AND NOTICE OF VIOLATION – IUPUI/INDIANA UNIVERSITY MEDICAL CENTER

Dear Mr. Swank:

On January 13, 2014 through January 17, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your campus in Indianapolis, Indiana. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action 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 apparent violation concerned the failure to secure licensed materials located in research laboratories, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting on January 17, 2014.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a Predecisional Enforcement Conference (PEC). Please contact Aaron T. McCraw at 630-829-9650 within ten days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03001609/2014001(DNMS); EA-14-028," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent 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 was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, it will be open for public observation. The NRC will issue a press release to announce the time and date of the conference. The NRC normally tries to schedule a PEC within 30 days of the date of the letter.

As your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Based on the results of this inspection, the NRC has also determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The violation concerned the failure to perform surveys to determine whether the Conrad Farms facility in Camby, Indiana, could be released as required by 10 CFR 20.1501(a)(1) and 10 CFR 20.1501(a)(2)(iii). These regulations require that reasonable surveys be performed to determine whether a facility meets the criteria under 10 CFR 20.1402 for release. While it is not your intention to release the facility, no licensed material has been used at the facility since June 2009. Title 10 CFR 30.36(d) requires, in part, that each licensee

notify NRC within 60 days after no principal activities have occurred at a facility for a period of 24 months if the facility contains residual radioactive material such that it is unsuitable for release. In this case, you have not performed surveys to determine that the facility is suitable for release nor have you notified the NRC that it is not suitable for release. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice, because the inspector identified the violation. The violation is described in detail in the enclosed inspection report.

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 NRC Information Notice 96-28 may be useful in preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, 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's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Geoffrey Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

/RA by AnnMarie Stone Acting for/

Patrick L. Louden, Director
Division of Nuclear Materials Safety

Docket Nos. 030-01609 and 030-09792
License Nos. 13-02752-03 and 13-02752-08

Enclosures:
1. Notice of Violation
2. Inspection Report Nos. 03001609/2014001(DNMS)
   and 03009792/2014001(DNMS)

cc w/encls: Mr. Mack Richard, Radiation Safety Officer
State of Indiana

notify NRC within 60 days after no principal activities have occurred at a facility for a period of 24 months if the facility contains residual radioactive material such that it is unsuitable for release. In this case, you have not performed surveys to determine that the facility is suitable for release nor have you notified the NRC that it is not suitable for release. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice, because the inspector identified the violation. The violation is described in detail in the enclosed inspection report.

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/RA by AnnMarie Stone Acting for/

Patrick L. Louden, Director
Division of Nuclear Materials Safety

Docket Nos. 030-01609 and 030-09792
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cc w/encls: Mr. Mack Richard, Radiation Safety Officer
State of Indiana

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Letter to Eric Swank from Patrick L. Louden, dated February 13, 2014

SUBJECT: NRC ROUTINE INSPECTION REPORT NOS. 03001609/2014001(DNMS) AND 03009792/2014001(DNMS) AND NOTICE OF VIOLATION – IUPUI/INDIANA UNIVERSITY MEDICAL CENTER

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NOTICE OF VIOLATION

IUPUI/Indiana University Medical Center
Indianapolis, Indiana

License No. 13-02752-03
Docket No. 030-01609

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on January 13, 2014 through January 17, 2014, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences: (1) The license has expired, (2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements, (3) No principal activities under the license have been conducted for a period of 24 months, or (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.
>
> Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. *Survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.
>
> Contrary to the above, as of January 13, 2014, the licensee failed to make surveys to ensure compliance with 10 CFR 20.1402, which provides radiological criteria for unrestricted use of facilities, or to notify the NRC within 60 days after no principal activities have occurred for a period of 24 months. Specifically, since June 2009, the licensee had not performed principal activities at the Conrad Farms facility in Camby, Indiana; had not performed surveys to determine whether the facility contained residual radioactivity such that it could be released for unrestricted use; and had not notified the NRC.

This is a Severity Level IV violation (Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, IUPUI/Indiana University Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, 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: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses 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.

Your response 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's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction. If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 13th day of February 2014.

U.S. Nuclear Regulatory Commission
Region III

Docket Nos.	030-01609 and 030-09792
License Nos.	13-02752-03 and 13-02752-08
Report Nos.	03001609/2014001(DNMS) and 03009792/2014001(DNMS)
EA No.	EA-14-028
Licensee:	IUPUI/Indiana University Medical Center
Facilities Inspected:	Downtown IUPUI/ Indiana University Medical Center campus 1100 West Michigan Street Indianapolis, Indiana Methodist Hospital campus I-65 and 21st Street Indianapolis, Indiana 6920 Parkdale Place Indianapolis, Indiana
Inspection Dates:	January 13, 2014 – January 17, 2014
Exit Meeting Date:	January 17, 2014
Inspectors:	Geoffrey Warren, Senior Health Physicist Ryan J. Craffey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

IUPUI/Indiana University Medical Center
NRC Inspection Report Nos. 03001609/2014001(DNMS) and 03009792/2014001(DNMS)

This was a routine inspection of licensed activities at IUPUI/Indiana University Medical Center, which was authorized to perform a variety of medical and research activities at its campuses in Indianapolis, Indiana.

The inspectors identified two unsecured laboratories, which contained an aggregate of approximately 3.1 millicuries (mCi) of iodine-125 (I-125), 4.3 mCi of sulfur-35 (S-35), 1 mCi of calcium-45 (Ca-45), 0.05 mCi of carbon-14 (C-14), and 5.5 mCi of tritium (H-3). This is an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801, which requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The root cause of the apparent violation is a misunderstanding of the requirement to secure licensed materials by some licensee laboratory personnel.

As corrective actions, the radiation staff: (1) collected the I-125 stock vials from one laboratory and placed them into secured storage under radiation safety staff's control, (2) visited the second laboratory to ensure that it remains locked when to individuals were present, (3) will issue non-compliance notices to the principal investigators in both laboratories, requiring a written response, and (4) will discuss the matter at the next radionuclide radiation safety committee meeting. In addition, the licensee will contact the principal investigators for any other laboratories that contain greater than 100 times the quantities of licensed materials listed in Appendix C to 10 CFR Part 20 to emphasize the importance of securing radioactive materials and requiring such investigators to provide a written response to indicate their method of securing such materials. Investigators possessing less than 100 times Appendix C quantities will also be reminded in writing of their responsibility to secure their materials. Compliance with security requirements will be evaluated during routine audits by the radiation safety staff.

The inspectors also identified a violation of 10 CFR 30.36(d) and 10 CFR 20.1501 concerning the licensee's failure to perform surveys to determine whether the Conrad Farms facility in Camby, Indiana, was suitable for release under 10 CFR 20.1402 or to notify the NRC and begin decommissioning under 10 CFR 30.36(d). No licensed material had been used at this facility since June 2009. The licensee will take steps to evaluate this situation and determine what actions they will take.

REPORT DETAILS

1 Program Overview

This was a routine inspection of IUPUI/Indiana University Medical Center, which is authorized under NRC Materials License Nos. 13-02752-03 and 13-02752-08 to operate a broadscope medical and research program, using licensed material for medical diagnosis, therapy, research, and instruction, among other uses. The licensee has 30,000 students and 3,000 faculty and staff at the campus in Indianapolis, Indiana. In addition to diagnostic nuclear medicine facilities, the licensee performs gamma stereotactic radiosurgery, high dose-rate remote afterloader (HDR) therapy, radiopharmaceutical therapies, microspheres treatments, and manual brachytherapy at University Hospital, and HDR, eye plaque, and radiopharmaceutical therapies at Methodist Hospital. Approximately 850 radiation worker personnel perform research in 200 to 250 laboratories under the supervision of 100 principal investigators. The radiation safety staff includes the full-time radiation safety officer (RSO), one alternate RSO, two assistant RSOs, one health physicist, a part-time waste technician, and administrative support.

2 Security of Licensed Materials

2.1 Inspection Scope

The inspectors reviewed the security of licensed materials by touring a variety of facilities, observing security procedures and conditions in the facilities, interviewing licensee personnel, and reviewing documentation and written procedures concerning security of licensed materials.

2.2 Observations and Findings

While touring a number of research laboratories where licensed materials was authorized to be used, the inspectors identified two research laboratories that contained unsecured radioactive material.

In one laboratory, an inspector and an escort from the radiation safety staff entered a laboratory in the Medical Sciences building where radiation workers were authorized to use licensed materials for research. The door to the laboratory was propped open with a cinder block, and the room itself was unoccupied; therefore, the inspector would have had unchallenged access to the room and any materials contained in the room without the escort present. The radiation safety staff member stated that there were no other means of limiting access to this laboratory during business hours. One member of the laboratory's staff was in an adjacent room, which was connected by an open doorway, but the individual had his back turned to the other lab and did not recognize the presence of visitors until the radiation safety staff member walked into the adjacent room to announce his presence. The laboratory staff member stated that another individual had just left the unoccupied lab for the day, and that he himself was preparing to leave and to lock the door in question behind him.

The laboratory contained I-125 in the form of iodination samples, liquid and dry waste, and unused portions of stock iodine. The inspector determined that approximately 3.1 mCi of unused I-125 remained in the vials. The samples and waste contributed an

additional but insignificant quantity of I-125. The inspector also noted the presence of two bagged containers in the same fume hood, one which was labeled that it contained 0.05 mCi of C-14, and another which was labeled that it contained 1 mCi of Ca-45.

In the second laboratory, the inspector and an escort from the radiation safety staff entered a laboratory in Building R3 where radiation workers were authorized to use licensed materials for research. There were two principal investigators authorized to work in the room. The door from the hallway into the laboratory was not locked and no licensee personnel were in the room; therefore, the inspector would have been able to enter the room without the escort. In the laboratory, the inspector observed two unsecured refrigerators and labeled containers for radioactive waste containing aggregate quantities of approximately 4.3 mCi of S-35 and 5.5 mCi of H-3. A laboratory staff member soon entered the room and was sent to get his principal investigator. The staff member stated that he believed that he was responsible for locking one door while personnel working for the other principal investigator were responsible for the door the inspector entered. The principal investigator stated that they would keep both doors locked when no personnel were in the laboratory until further plans could be made, but that he would like to discuss additional options for securing materials with the radiation safety staff.

The licensee's failure to secure radioactive materials in the two laboratories is an apparent violation of 10 CFR 20.1801, which requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Both laboratories are controlled areas as defined in 10 CFR 20.1003. The root cause of the apparent violation is a misunderstanding of the requirement to secure licensed materials by some licensee laboratory personnel.

As preliminary corrective actions, the radiation staff collected the I-125 stock vials from the first laboratory and placed them into secured storage under radiation safety staff's control. Radiation safety staff has verified that the second laboratory remains locked when no individuals were present. Principal investigators from both laboratories have stated that the laboratories will remain locked when they are not occupied. In addition, the licensee's RSO has stated that non-compliance notices will be issued to the principal investigators in both laboratories, requiring a written response, and that the matter will also be discussed at the next radionuclide radiation safety committee meeting.

In addition to the above actions, the licensee will contact the principal investigators for any other laboratories which contain greater than 100 times Appendix C quantities of licensed materials to emphasize the importance of securing radioactive materials, requiring such investigators to provide a written response to indicate their method of securing such materials. Investigators possessing less than 100 times Appendix C quantities will also be reminded in writing of their responsibility to secure their materials. Compliance with security requirements will be evaluated during routine audits by the radiation safety staff.

The inspectors observed that licensed materials were secured as required at other facilities, including additional research laboratories, nuclear medicine laboratories, areas containing materials for radiation oncology and irradiation, and waste storage areas.

2.3 Conclusions

The inspectors identified an apparent violation of 10 CFR 20.1801 concerning security of licensed materials in research laboratories. The licensee has taken actions and will take additional actions to restore compliance with the requirement and prevent recurrence of future similar violations.

3 Decommissioning Timeliness

3.1 Inspection Scope

The inspectors reviewed the use of licensed materials at the facilities listed on the license by observing such use at several facilities, reviewing documentation and procedures concerning use at such facilities, and interviewing licensee personnel about the use at each facility.

3.2 Observations and Findings

The inspectors determined that the licensee was authorized to use licensed material at Conrad Farms, a facility in Camby, Indiana. One principal investigator was authorized to use calcium-41 in three laboratories, but had never possessed such material. One of the three laboratories and four additional rooms had previously been authorized for the use of C-14, H-3, I-125, and phosphorus-32. The radiation safety staff had removed materials from these laboratories and performed closeout surveys on June 22, 2009. These surveys were intended as laboratory closeout surveys, not as decommissioning surveys; they did not include areas such as ventilation or plumbing, only areas used with the radioactive materials.

Title 10 CFR 30.36(d) requires, in part, that licensees notify the NRC and begin decommissioning within 60 days after no principal activities have occurred for a period of 24 months in a separate building or outdoor area which contains residual radioactivity such that the building or outdoor area cannot be released for unrestricted use. (The licensee had neither notified the NRC nor began decommissioning following the lack of use for a period exceeding two years). The RSO did not believe that there was any residual radioactivity in the building but could not state definitively that there was none. No determination had been made as to whether the facility could be released under the criteria specified in 10 CFR 20.1402.

Title 10 CFR 20.1501 which requires, in part, that each licensee make or cause to be made, surveys of areas, including the subsurface, that may be necessary for the licensee to comply with the regulations in this part; and are reasonable under the circumstances to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected. The failure to conduct a survey to determine that the facility could be released or to notify the NRC and begin decommissioning is a violation of 10 CFR 30.36(d) and 10 CFR 20.1501. Licensee personnel believed that the building was not subject to the requirements of 10 CFR 30.36 because some laboratories were still authorized for use.

In December 2013 the licensee ceased performing nuclear medicine activities at the authorized facility in Carmel, Indiana, and planned to perform decommissioning surveys in order to remove the location of use from the license and have it released for unrestricted use.

The inspectors observed that additional facilities authorized by the licenses were active and, thus, not subject to these requirements.

3.3 Conclusions

The inspectors identified a violation of 10 CFR 30.36(d) and 10 CFR 20.1501 concerning the licensee's failure to perform surveys to determine whether the Conrad Farms facility was suitable for release under 10 CFR 20.1402 or to notify the NRC under 30.36(d). The licensee will take steps to evaluate this situation and determine what actions they will take.

4 Other areas inspected

4.1 Inspection Scope

The inspectors observed licensed activities, interviewed licensee personnel, and reviewed selected records concerning use and storage of licensed materials and other aspects of the radiation safety programs. The inspectors observed diagnostic administrations of licensed materials, use of research and blood irradiators, and package receipt procedures. Licensee personnel demonstrated performance of daily HDR and nuclear medicine checks and administration of HDR and prostate implant procedures. The inspectors reviewed written directives for each therapy modality, records of personnel exposures, and records of radiation safety committee meetings. In addition, the inspectors performed confirmatory surveys in areas of radioactive materials use and in public areas.

4.2 Observations and Findings

Licensee personnel controlled access to licensed materials, in use and in storage, except as described above. The licensee monitored personnel for radiation dose when they used licensed materials, and no individuals received doses above regulatory limits. Licensee personnel were trained concerning the use of materials in nuclear medicine, radiation oncology, and research, and demonstrated their knowledge of radiation safety concepts and procedures. Survey instruments were properly calibrated and used. Radiation safety committee meetings included appropriate attendance and topics. Diagnostic and therapeutic procedures were performed in accordance with written procedures and good practices. Audits of the licensee's nuclear medicine program were comprehensive and identified areas for improvement. Confirmatory surveys indicated radiation levels consistent with licensee survey records and postings.

The licensee has taken corrective actions as described for the two violations cited in the Notice of Violation, dated December 23, 2011, concerning the licensee's failures to: (1) document the basis for release of patients who had been administered iodine-131 therapeutic doses as required by 10 CFR 35.75(c), and (2) address evaluation of prostate implants in the written procedure for such implants as required by 10 CFR 35.41(a). The licensee has also taken corrective actions as described for the

security-related violation cited in the Notice of Violation dated January 26, 2012. In addition, the violations have not recurred. Based on this, these violations are considered closed.

4.3 Conclusions

The inspectors did not identify any additional violations of NRC requirements.

5 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on January 17, 2014. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

Matthew Hadden, Assistant RSO
Mack Richard, RSO
Trent Mays, Alternate RSO
Eric Swank, Executive Director, Research Compliance

Attended exit meeting on January 17, 2014.