



INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY – INDIANAPOLIS

March 10, 2014

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

RE: Response to Apparent Violation & Response to Notice of Violation , Docket No. 030-01609, NRC License No. 13-02752-03

Dear Sir/Madam:

Attached please find our “RESPONSE TO AN APPARENT VIOLATION” and “RESPONSE TO NOTICE OF VIOLATION.” Should you have any questions, please don’t hesitate to contact me.

Sincerely,

Eric D. Swank
Executive Director of Research Compliance
Interim Assistant Vice President for Research Compliance
Indiana University

Cc: M. Richard, MS, CHP – IUMC/IUPUI Radiation Safety Officer
USNRC Region III Regional Administrator

LE07
RSN III

RESPONSE TO AN APPARENT VIOLATION
Inspection Report No. 03001609/2014001 (DNMS); EA-14-028

(1) Reason for Apparent Violation – The failure to secure licensed materials was noted in two separate laboratory areas. In one location (Medical Sciences (MS) Building), an authorized radionuclide user was in the room immediately adjacent to the laboratory and in close proximity to one entrance to that laboratory. However, there was a second entrance into the laboratory that was unlocked and not within the line of sight of the authorized radionuclide user and there were radioactive materials (~3 mCi of ^{125}I) in excess of 1000 times the 10 CFR 20, Appendix C quantities stored in a fume hood in that laboratory. Thus, it was determined by the NRC Inspector who entered with a member of the IUPUI/IUMC Radiation Safety Staff (RSS) from the other entrance that neither the laboratory nor the radioactive material were adequately secured. The authorized radionuclide user indicated that there had been some individuals present in the laboratory within the past hour, but they had left. He also indicated that he was preparing to leave and would lock the laboratory when he did so.

The other location (R3 Building) where it was determined licensed material was unsecured involved a laboratory with multiple entrances. In that case, two separate Permit Holders (PH) control access to that laboratory. One of the PHs indicated that the door that he primarily uses to access the laboratory was locked (that wasn't verified by the NRC Inspector); however, he indicated that the control of the other entrance which was not locked and was used to enter the laboratory by the NRC Inspector and the RSS member, was the responsibility of the other PH. All entrances to this laboratory were secured when the NRC inspector and RSS member left the area.

In both of the aforementioned situations, it appeared that the authorized radionuclide user and the PHs did not clearly understand the appropriate methods to secure licensed material, and in the case of the PHs, that the responsibility to secure licensed material is the responsibility of all individuals who share laboratory space. All licensed materials were secured following each of the aforementioned observations.

(2) Corrective Steps Taken and Results Achieved – As indicated in the Executive Summary of the inspection report, the RSS implemented a number of actions to mitigate these two security problems. Those actions include:

- A. The 3 mCi of ^{125}I was removed from the MS laboratory location by the RSS and taken to an area under the control of the RSS.
- B. A member of the RSS visited the laboratory in the R3 Building the following day to assure licensed materials were secured.
- C. The PHs responsible for the laboratories in the respective areas were notified by the RSS of the security problems noted during the inspection and provided written responses indicating their understanding of the need to secure licensed material and their assurance that such material would be secured in the future.
- D. PHs that currently possess in excess of 100 times the 10 CFR 20, Appendix C quantities were sent a questionnaire that specifically asked how licensed materials are secured in their authorized radionuclide laboratories. Responses to those questionnaires were

mandatory and were reviewed by the RSS. Based upon those responses, it appears that licensed material in the laboratories under those PHs is adequately secured.

- E. The RSS publishes a "Radiation Safety Newsletter" which goes out to all PHs to be shared with their authorized radionuclide users. In the February, 2014 edition of the newsletter, a section entitled "Laboratory Security" summarized the NRC's findings of unsecured licensed material and reiterated the importance of securing same.

(3) Corrective Actions Taken to Avoid Further Violations – The apparent violation and corrective actions will be included as an agenda item at the next meeting of the Radionuclide Radiation Safety Committee (RRSC). Input from the RRSC will be sought regarding additional ways to assure that licensed material is properly secured. The RSS will continue evaluating the security of licensed material during their routine audits of all areas where licensed material is used or stored and take appropriate action in situations where such security is inadequate.

(4) Date When Full Compliance Was Achieved – The issues in the identified labs were addressed as outlined above by the conclusion of the NRC inspection on January 17, 2014.

RESPONSE TO NOTICE OF VIOLATION
License No. 13-02752-03, Docket No. 030-01609

(1) Reason for the Violation – There currently exists an active Radionuclide Use Permit listing laboratory space in the Conrad Farms location as authorized for radionuclide use. Inasmuch as an active Radionuclide Use Permit allows for the use of radioactive material at any time, the Radionuclide Radiation Safety Committee (RRSC) and the IUPUI/IUMC Radiation Safety Office (RSO) considered that location under active use. As such, the NRC was neither notified that no radionuclide use had actually occurred at that location for a period greater than twenty-four (24) months, nor were surveys performed to demonstrate that the facility could be released for unrestricted use.

(2) Corrective Steps Taken and Results Achieved – In accordance with 10 CFR 30.36(d)(3), the NRC has been notified that there has been no use of radioactive material at the Conrad Farms location for more than twenty-four (24) months (enclosed). The RSO has contacted the individual responsible for the Radionuclide Use Permit listed above and it has been determined that no use of radioactive material is planned at the Conrad Farms location in the foreseeable future. Surveys have been performed and based upon the results of those surveys, that facility could be released for unrestricted use in accordance with 10 CFR 20.1402. However, we have requested an extension given the possibility of future use at this location under our broad scope license.

(3) Corrective Steps that Will Be Taken – As discussed above and in the enclosed letter, we will have requested an extension or exemption from the applicable requirements and will comply with the final determination of the NRC.

(4) Date When Full Compliance Will Be Achieved – Notification pursuant to 10 CFR 30.36(d)(3) has been made to the NRC in the enclosed communication dated XXXXX.



INDIANA UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION
RADIATION SAFETY - INDIANAPOLIS

March 7, 2014

U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Attn: Materials Licensing Branch

Re: A. Notification in Accordance with 10 CFR 30.36(d)(3) – NRC License No. 13-02752-03
B. Request for Alternative Decommissioning Schedule Under 10 CFR 30.36(h)(1)(i)
C. Request for Exemption from 10 CFR 30.36(d)(3)

Dear Sir/Madam:

A. Notification in Accordance with 10 CFR 30.36(d)(3)

During a recent Nuclear Regulatory Commission (NRC) inspection, it was determined that we had not notified the NRC Region III Office of that fact that no licensed material had been utilized at our Conrad Farms facility, located at 7610 West County Line Road, Camby, Indiana within the past twenty-four (24) months. This letter hereby serves as that notification.

B. Request for Alternative Decommissioning Schedule Under 10 CFR 30.36(h)(1)(i)

The Conrad Farms facility is an extension of the “Laboratory Animal Research Center (LARC)” which is located on the main IUPUI campus in Indianapolis, IN. While no licensed material has been utilized at the Conrad Farms location recently, three laboratories in that location are currently listed on an active Radionuclide Use Permit, meaning that licensed material could have been utilized under that permit at any time. The Radionuclide Radiation Safety Committee reviews and approves the renewal of each active Radionuclide Use Permit including the authorized locations of use at least bi-annually. The IUPUI/IUMC Radiation Safety Office has contacted that Permit Holder and after consultation with his technical staff, they have determined that used of licensed material in those laboratories will not take place in the foreseeable future and as such the Conrad Farm laboratories can be decommissioned and removed from their permit.

Even though the decommissioning of those laboratories will eliminate any radionuclide use at the Conrad Farms at the present, the location offers facilities unique to LARC operations and other research investigators may wish to utilize licensed material at that facility in the future. Although currently not in use, because of the potential for expansion of activity at this location, the university requests that total decommissioning of the Conrad Farms location be delayed, subject to the following conditions:

1. The IUPUI/IUMC Radiation Safety Office (RSO) had conducted “close-out” surveys in the past for some laboratories at Conrad Farms that were no longer authorized for radionuclide use. The RSO has since conducted additional surveys in those previously authorized laboratories to assure they meet the release criteria for unrestricted use (i.e. 10 CFR 20.1402). The RSO has also performed surveys of the three laboratories that were

still authorized for radionuclide use and found them to be free of contamination. Results of those surveys will be maintained for review during future NRC inspections.

2. Given the possibility of radionuclide use in the future, the Conrad Farms facility should remain listed as an authorized location of use on our NRC license; however, it will be placed on "standby" status until such time that radionuclide use is resumed or it is decided that no future use at that location will occur.
3. The administrative personnel responsible for the activities carried out at the Conrad Farms facility will notify the RSO of any actions (e.g. demolition, change in mission or transfer of ownership) that would require full decommissioning and notification of the NRC of the university's intent to forego all future use of radionuclides at that facility.
4. If it is determined that no future radionuclide use will occur at Conrad Farms, the NRC will be notified, a full decommissioning of the facility will be performed, the results forwarded to the NRC, and an amendment request submitted to remove that location from the NRC license.

C. Request for Exemption from 10 CFR 30.36(d)(3)

While the notification portion of this letter is intended to address the Conrad Farms facility, strict application of the decommissioning and notification requirements specifically driven by 10 CFR 30.36(d)(3) is a challenge under our broad scope license, and creates unnecessary and time-consuming paperwork for both our institution and the NRC. Research use and to a lesser degree, medical use of licensed material fluctuates within laboratories at our institution under our broad-scope license. Authorization and decommissioning of laboratory space is in a constant state of flux. Changes are continuously monitored by the Radiation Safety Office (RSO) and the Radionuclide Radiation Safety Committee (RRSC) and laboratory areas requesting the use of licensed material are approved in accordance with procedures that have been approved by the NRC. Likewise, as researchers and clinicians cease use of licensed materials in various laboratories, the RSO performs surveys in those laboratories and releases them for unrestricted use in accordance with 10 CFR 20.1402. The university understands that this level of oversight is incumbent on all broad-scope licensees.

According to 10 CFR 30.36(d)(3), if a period of 24 months has passed since the last use of licensed material in a given building, notification and formal decommissioning of that particular building is required. Decommissioning of an entire building is more difficult and time-consuming than decommissioning of individual laboratories. This is problematic because as long as a particular building includes existing laboratory space (or could be remodeled to include new laboratory space), use of licensed material could resume at any time, including 24 months or more after the last use. In that case, the time and effort expended by both the NRC and our staff has been wasted with no discernable benefit in terms of protecting our personnel or the general public from radiation hazards. As such, the university requests that NRC license number 13-02752-03 be exempted from the decommissioning and notification requirements specifically required by 10 CFR 30.36(d)(3).

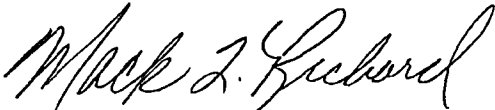
The university understands the basis of the requirements in 10 CFR 30.36(d)(3) is to prevent a licensed location from being abandoned and/or ownership transferred to another administrative entity while containing residual radioactivity that would exceed the requirements of 10 CFR

20.1402. In order to assure the NRC that such situations will not occur under this license, the university will implement the following actions:

1. Decommissioning surveys will continue to be performed for all laboratories that are no longer authorized for radionuclide use. Those laboratories will be released for unrestricted use providing they meet the requirements of 10 CFR 20.1402 and the surveys performed to demonstrate compliance with those requirements maintained for review during future NRC inspections.
2. Regardless of actual radionuclide use, as long as authorized radionuclide laboratories are listed on an existing Radionuclide Use Permit, those laboratories will be audited (including in-person visits by RSO staff) at least every six (6) months.
3. At such time there are no longer any authorized radionuclide laboratories within an existing building covered under the NRC license, the following actions will be implemented:
 - a. The RSO will request input from technical and/or administrative staff responsible for individual buildings and solicit information relative to the potential future use of radioactive material within that building. This information will be provided to the RRSC.
 - b. If the RRSC determines that radionuclide use may occur in the future, the affected building will be placed on "standby" status and the administrative personnel responsible for the activities carried out in that building will notify the RSO of any actions (e.g. demolition or transfer of ownership) that would require NRC notification and full decommissioning under 10 CFR 30.36(d).
 - c. If the RRSC determines that no future radionuclide use will occur in the affected building, the NRC will be notified, a full decommissioning of the building will be performed and the results forwarded to the NRC.
 - d. Documentation of the RRSC's actions will be maintained in the RRSC meeting minutes.

Should you have any questions regarding the contents of this letter, please do not hesitate to contact the IUPUI/IUMC Radiation Safety Office.

Sincerely,



Mack L. Richard, MS, CHP
Director of Health Physics
IUPUI/IUMC Radiation Safety Officer
Office of Research Administration

Cc: E. Swank