



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

June 3, 2009

Thomas Gillis, Ph.D., Lab Chief
Department of Health & Human Services
National Hansen's Disease Programs
United States Public Health Service
Laboratory Research Branch at LSU-SVM
Skip Bertman Drive
Baton Rouge, Louisiana 70803

SUBJECT: NRC INSPECTION REPORT 030-08380/09-001 AND NOTICE OF VIOLATION

Dear Dr. Gillis:

This refers to the routine, unannounced inspection conducted on April 22, 2009, at your facility in Baton Rouge, Louisiana, with continued in-office review. The inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel. Preliminary inspection findings were discussed with your Radiation Safety Officer (RSO) at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted with your RSO telephonically on June 1, 2009.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances that surround them are described in detail. The violations involved the failures to: 1) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas; 2) post each area or room in which licensed materials are used or stored; and 3) periodically (at least annually) review the radiation protection program content and implementation. These violations are being cited in the Notice because they were identified by the NRC during the inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," is enclosed. 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, Enclosure 1, and 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 Web site 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 available to the public without redaction.

Should you have any questions regarding this letter or the enclosed Notice, please contact Richard Leonardi at (817) 860-8187, or the undersigned at (817) 860-8287.

Sincerely,

/RA D. Blair Spitzberg for/

Vivian H. Campbell, Chief
Nuclear Materials Safety Branch-A

Docket No. 030-08380
License No. 17-14996-01

Enclosures:

- 1) Notice of Violation
- 2) Information Notice 96-28

cc w/enclosure:

Louisiana Radiation Control Program Director

cc w/enclosure
EECollins
AHowell
CLCain
VHCampbell
JEWhitten
RALeonardi
RITS Coordinator
NMSB-A
RIV Materials Docket File (5th Floor)

SUNSI Review Completed: RAL

ADAMS: X Yes _No Initials: RAL

X Publicly Available Non-Publicly Available Sensitive X Non-Sensitive

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RIV:DNMS:NMSB-A	C:NMSB-A
RALeonardi	VHCampbell
/RA/	/RA DBS for/
06/02/2009	06/03/2009

OFFICIAL RECORD COPY T=Telephone E=E-mail F=Fax

NOTICE OF VIOLATION

Department of Health & Human Services
Baton Rouge, Louisiana

Docket No. 030-08380
License No. 17-14996-01

During an NRC inspection conducted on April 22, 2009, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below.

- A. 10 CFR 20.1801 requires, in part, that the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, a controlled area is an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. An unrestricted area is defined as an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on April 22, 2009, the licensee did not secure from unauthorized removal or limit access to licensed material stored in lab No. 3520 in an unlocked container containing 2 millicuries of carbon-14, which was in a controlled area. Specifically, the licensee did not control access to the lab by locking the lab door during normal working hours, and routinely the lab door was propped open during periods of use with access by non-licensee individuals.

This is a Severity Level IV violation (Supplement IV).

- B. 10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, the licensee failed to periodically (at least annually) review the radiation protection program content and implementation. Specifically, the licensee had not reviewed the radiation protection program content and implementation during calendar years 2005-2008.

This is a Severity Level IV violation (Supplement IV).

- C. 10 CFR 20.1902(e) requires that the licensee post each area or room in which certain amounts of licensed material, specified in 20.1902(e), are used or stored, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on April 22, 2009, a caged-in compound on the Diagnostic Services Loading Dock (outside of the SVM building), an area or room in which 8.5 millicuries of carbon-14 was stored, was not posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

This is a Severity Level violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Department of Health & Human Services 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 IV 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 or severity level, (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 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.

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, United States Nuclear Regulatory Commission, Washington, DC 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).

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

Dated this 3rd day of June 2009