



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005**

March 3, 2005

Mr. Michael Smith, Laboratory Director
South Dakota Department of Health
Public Health Laboratory
615 East Fourth Street
Pierre, South Dakota 57501

SUBJECT: NRC INSPECTION REPORT 030-06373/05-001 AND NOTICE OF VIOLATION

Dear Mr. Smith:

This refers to the inspection conducted on February 9, 2005, at your facility in Pierre, South Dakota. This 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 your license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel. The preliminary inspection findings were discussed with Stacey Ellwanger, Acting Laboratory Director, at the conclusion of the onsite portion of the inspection, and a final telephonic exit briefing was conducted with her on February 22, 2005.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (enclosed). The violations are cited in the enclosed Notice of Violation (Notice). These violations are being cited because they were identified by the NRC during the inspection, and were repeat violations from our previous inspection conducted on August 2, 1999. However, the repeat violations were of low safety significance and no evidence of willfulness was identified. The repeat violations involved the failures to: (1) perform quarterly wipe tests on all sources used plus work surfaces where liquid aliquots of byproduct material were used, and (2) perform (at least annually) radiation protection program reviews for content and implementation for calendar years 1999-2003.

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 NRC 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.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at (800) 397-4209 or (301) 415-4737 or pdr@nrc.gov.

Should you have any questions concerning this inspection, please contact Mr. Richard Leonardi at (817) 860-8187 or the undersigned at (817) 860-8287.

Sincerely,

/RA/

Jeffrey Cruz, Chief
Nuclear Materials Inspection Branch

Docket No.: 030-06373
License No.: 40-11733-01

Enclosures:

1. Notice of Violation
2. NRC Information Notice 96-28
3. NRC Enforcement Policy, NUREG-1600

cc w/Enclosure 1:
South Dakota Radiation Control Program Director

bcc w/Enclosure 1 (via ADAMS distrib):
 PKHolahan
 CLCain
 JCruz
 JEWhitten
 RALeonardi
 KEGardin
 NMIB
 RIV Materials Docket File (5th floor)

SISP Review Completed: RL

ADAMS: Yes No Initials: RL

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

DOCUMENT NAME: s:\dnms!\nmib\!Leonardi\50637301.wpd

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RLeonardi	JEWhitten	J Cruz
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T=Telephone

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ENCLOSURE 1

NOTICE OF VIOLATION

South Dakota Department of Health
Pierre, South Dakota

Docket No. 030-06373
License No. 40-11733-01

During an NRC inspection conducted February 9-22, 2005, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

- A. License Condition 16 requires, in part, that licensed material be used in accordance with statements, representations, and procedures contained in the application dated July 29, 1994, and letters dated December 31, 1997, and June 30, 1998. In Item 4 of a letter dated December 31, 1997, the licensee committed to perform quarterly wipe tests on all sources used plus work surfaces where liquid aliquots of byproduct materials were used.

Contrary to the above, in calendar years 2000-2004, the licensee failed to perform quarterly wipe tests on two sealed sources (containing nominal activities of americium-241 and strontium-90) and perform quarterly wipe tests on work surfaces on which liquid aliquots (containing nominal activities of strontium-89, strontium-90, carbon-14, and americium-241) were used.

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

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

Contrary to the above, in calendar years 2000-2003, the licensee failed to periodically (at least annually) review the radiation protection program for content and implementation.

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

Pursuant to the provisions of 10 CFR 2.201, South Dakota Department of Health, Public Health Laboratory is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, 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 previous 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 3rd day of March 2005.