



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

July 9, 2008

PSI, Inc.
ATTN: Sebastian Ned Gregorio, R.Ph.
5523 Kendall Street
Boise, Idaho 83706

SUBJECT: NRC INSPECTION REPORT 030-35770/2008-001 AND NOTICE OF VIOLATION

Dear Mr. Gregorio:

This refers to the inspection conducted on March 26-28, 2008, at PSI, Inc. The inspection was an examination of activities conducted under byproduct material license 11-27705-01MD as it relates 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 you at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted with Mr. Mark Rotman on July 7, 2008.

Based on the results of this inspection, the NRC has determined that three violations of NRC requirements occurred. These violations involved the failure to: 1) conduct an annual audit; 2) monitor occupational exposures; and 3) obtain appropriate calibrations of radiation monitoring equipment. These violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's website at www.nrc.gov/about-nrc/regulatory/enforcement.html. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in the subject Notice. The violations are being cited in the Notice because they were identified by the NRC, rather than being self-identified by the licensee.

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.

PSI, Inc.

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Should you have any questions concerning this inspection, please contact Rick Muñoz at (817) 860-8220 or the undersigned at (817) 860-8287.

Sincerely,

/RA/ Anthony D. Gaines for

Vivian H. Campbell, Chief
Nuclear Materials Safety Branch A

Docket No.: 030-35770

License No.: 11-27705-01MD

Enclosures:

1. Notice of Violation
2. Excerpt from NRC Information Notice 96-28

cc w/enclosure:

Idaho Radiation Control Program Director

bcc w/Enclosure 1:

- ECollins
- CACasto
- ATHowell
- CLCain
- VHCampbell
- JEWhitten
- RRMuñoz
- RITS Coordinator
- NMSB-A
- RIV Materials Docket File (5th Floor)

SUNSI review completed: ADAMS: X Yes Initials: RRM
X Publicly Available X Non Sensitive

S:\DNMS\!NMIB\Reports in concurrence\PSI Inc NOV 08-01.doc Final: r:_dnms\

RIV:DNMS:NMSB-A	C:NMSB-B	C:NMSB-A
RMuñoz	JEWhitten	VHCampbell
/RA/	/RA/	/RA/ <i>ADGaines for</i>
6/24/08	6/27/08	7/08/08

OFFICIAL RECORD COPY

T=Telephone E=E-mail F=Fax

NOTICE OF VIOLATION

PSI, Inc.
Boise, Idaho

Docket No. 030-35770
License No. 11-27705-01MD

During a NRC inspection conducted from March 26 through July 8, 2008, three violations of NRC requirements were identified. In accordance with the Enforcement Policy, the violations are listed below:

1. 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, the licensee failed to periodically (at least annually) review the radiation protection program content and implementation. Specifically, between January 1, 2006, and December 31, 2006, the licensee did not review its radiation protection program.

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

2. 10 CFR 20.1502(a) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices.

10 CFR 20.1502(a)(1) requires, in part, that monitoring devices be used by adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

10 CFR 20.1201(a)(2)(ii) requires, in part, that each licensee shall control the occupational dose to individual adults to the annual limit of the shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

Contrary to the above, the licensee failed to monitor the occupational dose to the skin of any extremity by supplying appropriate personnel monitoring devices to individuals who were likely to receive a dose in excess of 10 percent of the limit. Specifically, from June 2006 through March 2008, radiopharmacy technicians were handling licensed radioactive material without wearing an extremity monitoring device (ring badge) and were likely to receive, in one year a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a)(2)(ii).

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

ENCLOSURE 1

3. License Condition 23, of byproduct materials license No.11-27705-01MD requires, in part, that the licensee shall conduct its program in accordance with license application dated June 28, 2001.

Appendix C, Item Number 10 of the license application entitled "Instruments," specifies in part, that the licensee will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Volume 13, "Program Specific Guidance About Radiopharmacy Licenses," dated September 1999. In addition, Item Number 10 states that instruments will be calibrated by other persons authorized by the NRC, an Agreement State, or licensing State to perform that service.

Contrary to the above, the licensee had a Ludlum Model 2200 radiation monitoring instrument Serial number 174825 used in their bioassay assessment program calibrated by a person not authorized by the NRC, Agreement State, or licensing State to perform that service. Specifically, in August 2007, the licensee calibrated the instrument and had not requested authorization and was not approved by the NRC to perform instrument calibrations.

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

Pursuant to the provisions of 10 CFR 2.201, PSI, Inc., 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, U.S. Nuclear Regulatory Commission, 612 East Lamar Blvd., Suite 400, Arlington, Texas 76011, 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 the 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.

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 are required to post this Notice within two working days.

Dated this _8_th day of July 2008.