UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 18, 2011

Docket Nos. 03001786
03008478
03017872
03037773

License Nos. 19-00296-10
19-00296-17
19-00296-20
19-00296-21

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
Department of Health & Human Services
National Institutes of Health
Building 1, Room 103
1 Center Drive, MSC0140
Bethesda, MD 20892-0140

SUBJECT: NRC INSPECTION REPORT NOS. 03001786/2011001, 03008478/2011001, 03017872/2011001, AND 03037773/2011002, AND NOTICE OF VIOLATION, DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, ROCKVILLE, AND BALTIMORE, MARYLAND

Dear Dr. Gottesman:

On April 4-8, 2011, Penny Lanzisera, Tara Weidner, Farrah Gaskins, Dennis Lawyer, John Nicholson, and Shawn Seeley of this office conducted a safety inspection at the National Institutes of Health (NIH). The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and your license. The inspection consisted of observations by the inspectors, interviews with personnel, and an examination of records. Additional information provided in your correspondence dated April 11 and May 9, 2011, was also examined as part of the inspection. The results of the inspection were discussed with Dr. Alfred Johnson, Director of the Office of Research Services, and other members of your organization at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has identified four violations of NRC requirements. Specifically, NIH: 1) did not determine their remote afterloader unit's timer linearity over the typical range of use as required by 10 CFR 35.633(b)(5); 2) approved an authorized user for the use of a remote afterloader unit under 10 CFR 35.600 without obtaining a written attestation signed by a preceptor authorized user who meets the requirements in 10 CFR 35.690, as required by Condition 11.B. of License No. 19-00296-10; 3) did not dispose of licensed material by decay in storage or transfer to an authorized recipient, as required by 10 CFR 20.2001; and 4) did not post a room adjacent to the cyclotron area with a "Caution Radiation Area" sign, as required by 10 CFR 20.1902. The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

The NRC has concluded that information regarding the reason for the violations and the

corrective actions taken and planned to prevent recurrence is already adequately addressed on the docket. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Med, Ind, & Academic Users;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc S. Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report
2. Notice of Violation

cc:
Nancy E. Newman, Radiation Safety Officer
State of Maryland

corrective actions taken and planned to prevent recurrence is already adequately addressed on the docket. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Med, Ind, & Academic Users;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas
Marc S. Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report
2. Notice of Violation

cc:
Nancy E. Newman, Radiation Safety Officer
State of Maryland

Distribution:
D. J. Holody, RI

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L19-00296-10.2011001.doc
SUNSI Review Complete: PLanzisera
After declaring this document "An Official Agency Record" it **will** be released to the Public.
To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy ML111390205 (LTR); ML111390158 (Rpt)

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		DNMS/RI	
NAME	PLanzisera PL		JNicholson JN		SSeeley SWS		TWeidner TW	
DATE	5/13/11		5/13/11		5/17/11		5/13/11	
OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI	E		
NAME	FGaskins FCG		DLawyer DRL		MFerdas MSF			
DATE	5/18/11		5/13/11		5/18/11			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Department of Health & Human Services
National Institutes of Health (NIH)

Docket Nos. 03001786
03008478
03017872
03037773
License Nos. 19-00296-10
19-00296-17
19-00296-20
19-00296-21

During an NRC inspection conducted on April 4-8, 2011, as well as in-office review of information provided by NIH on April 11 and May 9, 2011, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.633(a) requires, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements following replacement of the source.

10 CFR 35.633(b)(5) requires, in part, remote afterloader full calibration measurements to include a determination of timer linearity over the typical range of use.

Contrary to the above, in 2010, NIH performed high dose rate remote afterloader (HDR) full calibration measurements that did not include a determination of timer linearity over the typical range of use. Specifically, after source replacement, timer linearity was measured over 200 seconds; however, the typical treatment time was approximately 500 seconds. In addition, on August 11, 2010, timer linearity was not determined during the full calibration, as required.

This is a Severity Level IV violation (Section 6.3).

B. Condition 11.B. of License No. 19-00296-10 requires, in part, that individuals designated to work as authorized users, as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.

10 CFR 35.690(b)(3) requires, in part, that the written attestation must be signed by a preceptor authorized user who meets the requirements in 10 CFR 35.57 or 35.690 for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Contrary to the above, on March 26, 2009, NIH's Radiation Safety Committee designated an individual to work as an authorized user, as defined in 10 CFR 35.2, and did not obtain a written preceptor attestation from a preceptor authorized user who met the requirements in 10 CFR 35.57 or 35.690. Specifically, the written preceptor attestation provided to the Radiation Safety Committee was signed by a authorized medical physicist instead of an authorized user.

This is a Severity Level IV violation (Section 6.3).

C. 10 CFR 20.2001 requires, in part, that a licensee dispose of licensed material only by transfer to an authorized recipient as provided in 10 CFR 20.2006 or in the regulations in parts 30 and 61 of this chapter, or by decay in storage.

Contrary to the above, on May 4 and June 28, 2010, NIH did not dispose of licensed material by transfer to an authorized recipient as provided in 10 CFR 20.2006 or in the regulations in parts 30 and 61 of this chapter, or by decay in storage. Specifically, nanocurie quantities of bromine-76/77 and zirconium-88/89 were disposed to the normal trash prior to decay, which caused local landfill radiation detectors to alarm.

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

D. 10 CFR 20.1902(a) requires, in part, that a licensee post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

Contrary to the above, as of April 5, 2011, NIH did not post a radiation area located in a room adjacent to the cyclotron area with a sign bearing the radiation symbol and the words "CAUTION, RADIATION AREA." Specifically, a room located adjacent to the cyclotron charcoal exhaust filter room had a measurable reading of 12 milliRoentgen per hour 20 minutes following a transfer of carbon-11 and 5 milliRoentgen per hour 45 minutes following the transfer and was not posted as required.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket. Therefore, you are not required to respond to this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if

you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This _18_ day of _May_ 2011