



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

November 20, 2006

Docket No. 03033331

License No. 37-30084-01

Abdurrahman Unal, M.D.
Medical Director, and Radiation Safety Officer
Keystone Oncology, LLC
775 South Arlington Avenue
Harrisburg, PA 17109

SUBJECT: INSPECTION 03033331/2006002, KEYSTONE ONCOLOGY, LLC,
HARRISBURG, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Dr. Unal:

On October 24, 2006, Shirley Xu of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Dr. Unal and Dr. Ying of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in a file dated October 24, 2006. 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 addition, as noted during the inspection and discussed with your staff, since the cage housing the HDR unit is not bolted to the wall or floor, security of the HDR unit must be maintained through constant surveillance or locking the treatment room door.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

A. Unal
Keystone Oncology, LLC

2

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Pennsylvania

A. Unal
Keystone Oncology, LLC

3

Distribution:
D. J. Holody, RI

DOCUMENT NAME: C:\FileNet\ML063240519.wpd

SUNSI Review Complete: SXu

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

| | | | | | | |
|--------|----------|---|------------|---------|--|--|
| OFFICE | DNMS/RI | N | DNMS/RI | DNMS/RI | | |
| NAME | Sxu PJH1 | | PHenderson | | | |
| DATE | 11/20/06 | | 11/20/06 | | | |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Keystone Oncology, LLC
Harrisburg, PA

Docket No. 03033331
License No. 37-30084-01

During an NRC inspection conducted on October 24, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.633(b) requires, in part, that full calibration measurements must include determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, the license did not verify timer linearity over the typical range of use. Specifically, as of October 24, 2006, the licensee had not performed timer linearity checks over the typical range of use during HDR calibrations.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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, within 30 days of the date of the letter transmitting this Notice of Violation (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.

Dated This 20 day of November, 2006