

March 27, 2009

EA-09-067

Mr. Chris Achtien
Executive Director
Central Indiana Cancer Centers
1346 East County Line Road
Indianapolis, IN 46227

SUBJECT: NRC INSPECTION REPORT NO. 030-35383/2009-001(DNMS) – CENTRAL
INDIANA CANCER CENTERS

Dear Mr. Achtien:

This refers to the inspection conducted on February 18-19, 2009, at the Indianapolis and Greenfield, Indiana facilities. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The preliminary findings of the inspection were discussed with Dr. Yun Wang of your staff at the conclusion of the inspection. The enclosed report presents the results of this inspection. On February 26, 2009, the inspection findings were discussed with you and Dr. Yun Wang during a telephonic exit meeting.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, five apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The inspector identified five apparent violations involving the failure to: (1) secure an iridium-192 sealed source from unauthorized removal or access while not in storage (10 CFR 20.1802); (2) secure several germanium-68 sealed sources and fluorine-18 patient doses from unauthorized removal or access while not in storage (10 CFR 20.1802); (3) request a license amendment to add two locations of use and storage for licensed material permitted by 10 CFR 35.200; (4) perform removable contamination surveys of incoming packages containing licensed material (10 CFR 20.1906(b)); and (5) perform weekly removable contamination surveys in radiopharmaceutical administration areas (Condition 19).

Enclosure 2 Contains Sensitive Unclassified Non-Safeguards Information. Upon Separation, This Letter and Enclosure 1 are Decontrolled.
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The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the preliminary inspection exit meeting on February 19, 2009, and with you, via telephone, on February 26, 2009. As a result, it may not be necessary for you to provide a written response to the apparent violations or attend a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy.

However, before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Kenneth J. Lambert at 630-829-9633 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in Inspection Report No. 030-35383-2009-001(DNMS); EA-09-067" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (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. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

The NRC noted that four of the five apparent violations were related to accelerator-produced radioactive material for which the NRC retained regulatory jurisdiction on November 30, 2008. Please review all aspects of your radiation safety program to ensure that all activities involving accelerator-produced radioactive material and radium-226 are in compliance with NRC regulations.

Based on the results of this inspection, the NRC has also determined that three Severity Level IV violations of NRC requirements occurred. These violations involved the failure to: (1) place Radioactive Yellow II labels on the opposite sides of a package containing an iridium-192 sealed source being transported on public highways (49 CFR 172.403); (2) mark the outside of the packaging being offered for transport as a Type A package (49 CFR 172.310); and (3) have the proper shipping name and identification number on a shipping package containing an iridium-192 sealed source being transported on public highways (49 CFR 172.301). These violations were evaluated in accordance with the NRC Enforcement

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Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>)." The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they were identified by the NRC.

The NRC has concluded that information regarding the reason for the violations cited in the Notice, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in Inspection Report No. 030-35383/2009-001(DNMS). Therefore, you are not required to respond to the cited violations unless the description within the inspection report 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, its enclosures, and your response, if you choose to provide one, 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.

Sincerely,

/RA Andrew Persinko, Acting For/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No.: 030-35383
License No.: 13-32241-01

cc: Dr. Yun Wang, Radiation Safety Officer

Enclosures:

1. Notice of Violation
2. Inspection Report 030-35383/2009-001(DNMS) (Security-Related Information)
3. Excerpt from NRC Information Notice 96-28

DISTRIBUTION:

See next page

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Letter to Chris Achtien from Steven A. Reynolds dated March 27, 2009

SUBJECT: NRC INSPECTION REPORT NO. 030-35383/2009-001(DNMS) – CENTRAL
INDIANA CANCER CENTERS

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NOTICE OF VIOLATION

Central Indiana Cancer Centers
Indianapolis, Indiana

Docket No. 030-35383
License No. 13-32241-01

During an NRC inspection conducted on February 18-19, 2009, with continuing NRC review through February 26, 2009, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

1. Title 49 CFR 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with two RADIOACTIVE YELLOW II labels on opposite sides of the package.

Contrary to the above, as of February 19, 2009, the licensee transported on public highways licensed material (iridium-192) without the required RADIOACTIVE YELLOW II labels on opposite sides of the package.

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

2. Title 49 CFR 172.310 states, in part, that for each package containing radioactive materials, the packaging must be marked on the outside of the package, in letters at least 13 mm (0.5 inch) high, with the words "TYPE A."

Contrary to the above, as of February 19, 2009, the licensee transported on public highways licensed material (iridium-192) in a TYPE A package which was not marked "TYPE A."

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

3. Title 49 CFR 172.301 states, in part, that each person, who offers a hazardous material for transportation in a non-bulk packaging, marks the package with the proper shipping name and identification number.

Title 49 CFR 171.8 defines non-bulk packaging, in part, as which has: (1) a maximum capacity of 450 L (119 gallons) or less as a receptacle for a liquid; or (2) a maximum net mass of 400 kg (882 pounds) or less, and a maximum capacity of 450 L (119 gallons) or less as a receptacle for a solid; or (3) a water capacity of 454 kg (1000 pounds) or less as a receptacle for a gas.

Contrary to the above, as of February 19, 2009, the licensee offered a package containing iridium-192, a hazardous material, for transportation in a non-bulk packaging and failed to mark the package with the proper shipping name or identification number.

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

Enclosure 1

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Report No. 030-35383/2009-001(DNMS). 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, 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, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 27th day of March, 2009.