

May 27, 2009

EA-09-067

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

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

Dear Mr. Ahtien:

This refers to the inspection conducted on February 18 and 19, 2009, at your facilities in Indianapolis and Greenfield, Indiana. The purpose of the inspection was to examine activities conducted under your license as they related to safety and compliance with the Commission's rules and regulations and with the conditions in your license. During the inspection, apparent violations of U.S. Nuclear Regulatory Commission (NRC) requirements were identified by the NRC inspector. Details regarding the apparent violations were provided in NRC Inspection Report No. 030-35383/2009-001(DNMS), dated March 27, 2009.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. On April 13, 2009, Dr. Yun Wang, the Radiation Safety Officer for Central Indiana Cancer Centers, informed Mr. Kenneth Lambert, Acting Chief, Materials Inspection Branch, that Indiana Cancer Centers declined a Predecisional Enforcement Conference and declined to submit a written response.

Therefore, based on the information developed during the inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is the result of your staff's failure to secure an iridium-192 sealed source from unauthorized removal or access while the high dose rate afterloader device, in which the source was located, was being moved from one location to another. The NRC determined that the root cause of the violation was a misunderstanding on your staff's part of the NRC's requirements about the need to control radioactive material at all times.

The violation is of concern to the NRC because the failure to control radioactive material could lead to a member of the public receiving an unnecessary exposure to radioactive material if the high dose rate afterloader device was stolen and the source was exposed. In this case, no actual consequences occurred. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether

credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy. In its March 27, 2009, letter, the NRC delineated the corrective actions that your staff had taken and those that were planned to be taken, as provided to the inspector. The corrective actions taken included retraining all individuals about the requirements associated with controlling radioactive sources. Those that you planned to take included discussing this issue at the next Radiation Safety Committee meeting to ensure all actions have been taken to maintain compliance with NRC regulations.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the inspection report, dated March 27, 2009. 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 to the above violation, the inspection report also identified apparent violations that involved naturally occurring or accelerator produced radioactive materials (NARM). The Energy Policy Act of 2005 (EPAct) expanded the definition of byproduct material to include NARM and placed the material under the NRC's jurisdiction. On November 30, 2007, the NRC published a Notice of Waiver Termination for licensees in the State of Indiana which stated, in part, that the NRC was terminating the waiver for persons possessing accelerator-produced radioactive material or discrete sources of radium-226. The Notice further stated that the final rule allowed an additional 6-month period from the effective date of the final rule to apply for a license amendment, i.e., May 30, 2008.

The NRC has determined violations of NRC regulations occurred that involved NARM. These violations included failure to maintain positive control over or to secure a mobile Positron Emission Tomography (PET) scanner at all times; use of the PET scanner, and other NARM, at locations not addressed on your NRC license; and not performing wipes for contamination of incoming packages or on a weekly basis at locations where NARM was used. During the inspection, you described your corrective actions for these violations to the inspector. Your immediate corrective actions included retraining technicians to ensure licensed material is secure at all times and that they knew to perform contamination wipes. You submitted an amendment to NRC to approve two locations for 10 CFR 35.200 activities. You also committed to using a borrowed wipe counting system until either the old system was repaired or a new system can be purchased for the PET trailer. As a long-term corrective action, you committed to also discussing these violations during the next Radiation Safety Committee meeting to ensure all actions have been taken to maintain compliance with NRC regulations.

These violations were also evaluated in accordance with the NRC Enforcement Policy. The failure to secure the material is normally characterized as a Severity Level III violation, while the

remaining violations are normally characterized as Severity Level IV violations. However, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion for these violations in accordance with Enforcement Guidance Memorandum EGM-09-004 (ML091340060) because: (1) this was the first inspection after the effective date of the new requirements; (2) you did not recognize that the requirements applied to you because of the type of material involved; and (3) there was no actual safety, health or security consequences as a result of these violations. However, further violations involving NARM could result in enforcement action in accordance with the NRC Enforcement Policy.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA/

Mark A. Satorius  
Regional Administrator

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

Enclosure:  
Notice of Violation

cc w/encl: State of Indiana

remaining violations are normally characterized as Severity Level IV violations. However, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion for these violations in accordance with Enforcement Guidance Memorandum EGM-09-004 (ML091340060) because: (1) this was the first inspection after the effective date of the new requirements; (2) you did not recognize that the requirements applied to you because of the type of material involved; and (3) there was no actual safety, health or security consequences as a result of these violations. However, further violations involving NARM could result in enforcement action in accordance with the NRC Enforcement Policy.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

/RA/

Mark A. Satorius  
Regional Administrator

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

Enclosure:  
Notice of Violation

cc w/encl:  
State of Indiana

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DATE	05/21/09	05/21/09	05/22/09	05/19/09	05/27/09	05/27/09

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1. OE concurrence received via e-mail from K. Day on May 19, 2009.

Letter to Chris Achtien from Mark A. Satorius dated May 27, 2009

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

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## NOTICE OF VIOLATION

Central Indiana Cancer Centers  
Indianapolis, Indiana

Docket No. 030-35383  
License No. 13-32241-01  
EA-09-067

During an NRC inspection conducted on February 18 and 19, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, as of February 18, 2009, the licensee did not control and maintain constant surveillance over licensed material while the material was in an unrestricted area and the material was not in storage. Specifically, on several occasions while transporting a High Dose Rate (HDR) Afterloader, which contained the radioactive material, licensee personnel left the HDR containing the source in an unlocked vehicle for several minutes while moving other equipment associated with the HDR that was also being transported in the vehicle. During these periods, the licensee did not control or maintain constant surveillance over the source.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-35383/2009-001(DNMS), dated March 27, 2009. 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 EA-09-067," 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, 2443 Warrenville Road, Suite 210, Lisle IL 60532, 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, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

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, your 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 27<sup>th</sup> day of May 2009

ENCLOSURE