

June 8, 2007

EA-07-102, EA-07-126

Maureen P. Barnes
Vice President, Risk Management
The Cooper Health System
Robert Wood Johnson Medical School at Camden
One Cooper Plaza
Camden, NJ 08103

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 2006-001)

Dear Ms. Barnes:

This letter refers to the NRC inspection conducted during (1) onsite inspections on December 18 and 20, 2006, and January 5, 2007, at the above address and at your other sites in Camden, Voorhees, Cherry Hill, and Willingboro, New Jersey, as well as (2) reviews of additional information provided in your correspondence dated December 28, 2006, February 16 and March 16, 2007, electronic mail dated April 3, 2007, and updated procedures provided on May 11, 2007, from the NRC Region I office. During this inspection, the NRC identified two apparent violations involving the failure to verify that a high dose rate afterloader (HDR) treatment was administered in accordance with the treatment plan and written directive, and the failure to report to the NRC a medical event. The inspector discussed the findings of the inspection with you and members of your staff during an exit meeting on May 11, 2007. The findings of the inspection were also described in detail in NRC Inspection Report 03002512/2006001 sent to you on May 22, 2007.

In our May 22, 2007, letter we informed you that the NRC was considering escalated enforcement action for the two apparent violations. The May 22, 2007, letter also provided you an opportunity to either respond in writing to this apparent violation, or attend a predecisional enforcement conference (PEC). You subsequently informed the NRC on May 23, 2007, that you did not request a PEC, and you did not wish to provide a written response.

Therefore, based on the inspection and information provided, the NRC has determined that two violations of NRC requirements occurred at your facility. 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 first violation, which occurred on November 9, 2006, involved failure to meet requirements set forth in 10 CFR 35.41(b)(2). Specifically, Cooper Health System failed to: (1) verify that an HDR treatment for cancer of the cervix was administered in accordance with the treatment plan and written directive; and, (2) have an adequate written procedure to verify such administrations are performed in accordance with the treatment plan and written directive. In this case, the

reference source position for one of two applicators was incorrectly entered into the treatment console, resulting in delivery of a fractional dose that deviated from the prescribed fractional dose by more than 50 rem and more than 50% of the prescribed dose. This resulted in a medical event at the facility.

The first violation is of concern to the NRC because failure to have adequate procedures to verify that the administration is in accordance with the treatment plan and written directive could result in medical events including those where overdose occurs. In this case, there was no actual consequence since the patient received an under-dose for one fraction of a five fraction treatment, and an additional treatment fraction was subsequently administered to ensure that the patient received a sufficient dose. In accordance with Supplement VI.B.3 of the Enforcement Policy, this violation has been classified at Severity Level (SL) III.

The second violation involved the failure to report the medical event to the NRC in accordance with 10 CFR 35.3045 (c) and (d). Although the Radiation Safety Officer (RSO) and Cooper Health System management were not aware that a medical event had occurred until the inspector identified it, three of your staff members, including the chief of physics, were aware that a treatment error had occurred and did not make the appropriate internal reports within your organization. This violation is of concern to the NRC because the failure to report the treatment error to the Radiation Oncology Department Quality Assurance Committee and the RSO, delayed the opportunity to identify weaknesses in procedures and systems. In accordance with Supplement VI.C.5 of the Enforcement Policy, this violation has also been classified at SL III.

A base civil penalty in the amount of \$3,250 is normally considered for a Severity Level III violation, in accordance with the Enforcement Policy. Since your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included: (1) instituting a policy that HDR plans are never to be modified at the treatment console; (2) instituting a program of in-service training for authorized users (AUs) and authorized medical physicists (AMPs) regarding NRC medical event reporting requirements; (3) adopting written criteria to identify treatment errors to be reviewed by the Radiation Oncology Department Quality Assurance Committee; (4) adopting a policy on event reporting in accordance with the requirements of multiple agencies, including reporting of medical events to the NRC; (5) having the Clinical Director of Radiation Oncology conduct an AU peer review of the event and the Director of Physics (who is an AMP), Clinical Director of Radiation Oncology, and Chief of Radiation Oncology conduct a peer review of 2006 HDR cases; (6) extending the program of HDR written directive audits to include quarterly audits by the RSO, an AMP, and an AU; and, (7) contracting with the Chief Clinical Physicist from Fox Chase Cancer Center to perform a review of the brachytherapy program.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for the SL III violations. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, as well as in your correspondence dated December 28, 2006, February 16 and March 16, 2007, and the April 3, 2007, electronic mail and updated procedures provided on May 11, 2007. 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. 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 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov>.

Sincerely,

/RA/ Original Signed By: Marc Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 03002512
License No. 29-08285-01

Enclosure: Notice of Violation

cc w/encl:
State of New Jersey

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, as well as in your correspondence dated December 28, 2006, February 16 and March 16, 2007, and the April 3, 2007, electronic mail and updated procedures provided on May 11, 2007. 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. 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 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov>.

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 03002512
License No. 29-08285-01

Enclosure: Notice of Violation

cc w/encl:
State of New Jersey

DISTRIBUTION:

ADAMS (PARS)	CMiller, FSME	DScrenci, PAO-RI
SECY	GPangburn, FSME	NSheehan, PAO-RI
CA	JSchlueter, FSME	BHolian, RI
OEMAIL	DRathbun, FSME	MMiller, RI
OEWEB	Enforcement Coordinators	KFarrar, RI
L Reyes, EDO	RII, RIII, RIV	DHolody, RI
WKane, DEDR	LLopez, OE	ADeFrancisco, RI
MVirgilio, DEDMRT	OSamuel, OE	RSummers, RI
CCarpenter, OE	MElwood, OGC	CO'Daniell, RI
SMerchant, OE	EHayden, OPA	SVillar, RI
LSreenivas, OE	HBell, OIG	RIDNMS_Mail
BJones, OGC (Bradley)	GCaputo, OI	Region I OE Files (with
LChandler, OGC	LTremper, OCFV	concurrences)

SUNSI Review Complete: __pjh__ (Reviewer's Initials)

ADAMS Accession No.: ML071590326

DOCUMENT NAME: C:\FileNet\ML071590326.wpd

After declaring this document "An Official Agency Record" it will/will not be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/RC	RI/ORA	RI/RA
NAME	*ADeFrancisco	*PHenderson/slg for	*BHolian	*KFarrar	*DHolody	SCollins/mld for
DATE	06/01/07	06/01/07	06/04/07	06/06/07	06/07/07	06/07/07

OFFICIAL RECORD COPY

*see previous concurrence page

NOTICE OF VIOLATION

The Cooper Health System
Camden, New Jersey

Docket No. 03002512
License No. 29-08285-01
EA-07-102, 07-126

During an NRC inspection conducted on December 18 and 20, 2006, and January 5, 2007, as well as during reviews of additional information provided in your correspondence dated December 28, 2006, February 16 and March 16, 2007, electronic mail dated April 3, 2007, and updated procedures provided on May 11, 2007, for which an exit meeting was held on May 11, 2007, the NRC identified violations of NRC requirements. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.41(a) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b)(2) requires, in part, that the licensee's procedures for administration of licensed material requiring a written directive include verification that the administration is in accordance with the treatment plan and written directive, checking both manual and computer-generated dose calculations, and verifying that any computer-generated dose calculations are correctly transferred to the consoles of therapeutic medical units authorized by 10 CFR 35.600.

Contrary to the above, the licensee did not develop, implement, and maintain written procedures to verify that administrations are in accordance with the treatment plan and written directive, check both manual and computer-generated dose calculations, and verify that computer-generated dose calculations were correctly transferred to the console of a therapeutic medical unit authorized by 10 CFR 35.600. As a result, on November 9, 2006, the licensee failed to verify that a high dose rate remote afterloader brachytherapy treatment was administered in accordance with the treatment plan and written directive in that a positional change of 20 centimeters (cm) was entered into the unit console instead of a change of 2 cm, resulting in a 77 percent under-dose for that treatment fraction to the patient.

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

- B. 10 CFR 35.3045(a)(1)(iii) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the administration of radiation from byproduct material results in a dose that differs from the prescribed dose by more than 50 rem to an organ or tissue and the fractionated dose differs from the prescribed dose, for a single fraction, by 50 percent or more.

10 CFR 35.3045(c) requires that the licensee notify the NRC Operations Center by telephone no later than the next calendar day of the discovery of the medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after discovery of the medical event.

Notice of Violation

Contrary to the above, as of December 18, 2006, the licensee had not reported, either by telephone or in writing, an event that occurred on November 9, 2006 in which the reporting criteria of 10 CFR 35.3045(a)(1)(iii) were met and the event did not result from patient intervention. Specifically, on November 9, 2006, a high dose rate remote afterloader treatment fraction was delivered in which the source was positioned outside of the patient's body for a portion of the treatment. The dose delivered to the treatment site differed from the prescribed dose by more than 50 rem to an organ or tissue and the fractionated dose differed from the prescribed dose, for a single fraction, by 50 percent or more. Licensee personnel discovered the treatment error on the day it occurred, but failed to inform management or the Radiation Safety Officer, and did not recognize that this event met the reporting criteria of 10 CFR 35.3045(a)(1)(iii). As a result, the NRC was not provided a verbal report the next day, nor a written report within 15 days.

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

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter regarding the violations unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond to this violation, clearly mark your response as a "Reply to a Notice of Violation, EA-07-102, 07-126" 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 I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, the 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 may be required to post this Notice within two working days.

Dated this 8th day of June 2007.