



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

October 3, 2012

EA-12-090
NMED: 120067

Ms. Judy Blauwett
Senior Vice President of Operations
Avera McKennan Hospital
1325 South Cliff Avenue
Sioux Falls, South Dakota 57117-5045

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$11,200 (NRC SPECIAL INSPECTION REPORT 030-11252/2012-001)

Dear Ms. Blauwett:

This refers to the special inspection conducted from January 30 through February 2, 2012, at Avera McKennan Hospital (licensee) located in Sioux Falls, South Dakota, with continued in-office review through June 13, 2012. The inspection was conducted in response to medical events that occurred on January 16 and 17, 2012. Your radiation safety officer reported two events to the NRC on January 17, 2012. Your initial report states that the events involved radiation underexposures to a patient undergoing brachytherapy procedures. Your radiation safety officer updated the report on January 31, 2012, to inform the NRC that, in addition to the underexposures to the intended treatment site, exposures to an unintended site on the patient's skin also occurred. Avera McKennan Hospital initiated corrective actions as soon as the first event was identified on January 16, 2012. However, a similar event occurred on January 17, 2012. On June 13, 2012, the NRC issued an inspection report detailing the circumstances surrounding the events (ML12166A427).

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated July 12, 2012 (ML12200A299), you provided a written response to the apparent violation.

Based on the information developed during the special inspection and the information that you provided in your response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. This 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 involved a failure to develop, implement, and maintain written procedures, that provide high confidence, that each treatment is in accordance with the physician's written directive as required by 10 CFR 35.41. This resulted in two separate medical events while treating a patient with a high dose-rate remote afterloader.

The first event occurred when your personnel incorrectly measured the length of the catheter and programmed the incorrect catheter length into the high dose-rate remote afterloader. As a result, the first of ten scheduled treatment fractions was delivered to the wrong location. Later that same day, additional personnel identified the error, entered corrected treatment parameters in the high dose-rate remote afterloader treatment console, and then delivered the second fraction to the intended location as prescribed in the written directive. However, the incorrect treatment parameters of the first, incorrect fraction were saved in the treatment console, along with the corrected parameters. The next morning, when delivering the third fraction, your personnel used the program file with the original parameters from the previous day to, once again, deliver the treatment with the wrong catheter length. This error resulted in the second and repeated medical event. That afternoon, your personnel identified the error before delivering the fourth fraction. To ensure that the correct program file would be used for the remaining fractions delivered to the patient, personnel removed the file containing the incorrect parameters from the treatment console. On January 17, 2012, you reported the events to the NRC in accordance with 10 CFR 35.3045(a)(1).

The consequences to the patient from an approximately 27 Gray (2700 rad) skin dose to the wrong site progressed from an initial small area of erythema (redness of the skin) to a larger area of ulceration by five months after treatment and the appearance of blackened colored tissue that resulted in a referral for consultation to treat the patient with hyperbaric oxygen therapy. The NRC has determined that the violation involves a substantial programmatic failure to develop and implement procedures for medical administrations requiring a written directive. The substantial programmatic failure was demonstrated by the licensee's failures to implement the following elements in its procedures: (1) verify that the administration was in accordance with the treatment plan and written directive in accordance with 10 CFR 35.41(b)(2), (2) check both manual and computer-generated dose calculations in accordance with 10 CFR 35.41(b)(3), and (3) verify that any computer-generated dose calculations were correctly transferred into the consoles of therapeutic medical units in accordance with 10 CFR 35.41(b)(4). Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level II.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$5,600 is considered for a Severity Level II violation. The NRC has considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has noted that, after the first fraction, your personnel identified that the incorrect catheter length had been entered in to the treatment console. However, the NRC has determined that credit for Identification for the violation and the entirety of the circumstances in which it occurred is not warranted. Specifically, there was a repeated occurrence of the same failures leading to a second and repeated medical event to the patient. Further, Avera McKennan Hospital did not identify that the lack of procedures was the root cause of the two medical events until discussions with the NRC inspection team occurred during the week of January 30, 2012. Prior to those discussions, you had focused on catheter measurement error and the selection of the wrong treatment plan at the high dose-rate remote afterloader console as isolated deficiencies.

The NRC has determined that credit was warranted for *Corrective Action* for the violation based on prompt and comprehensive corrective actions after the second medical event was discovered and with input from the inspection. Immediate corrective actions included, but were not limited to, a reorganization of the radiation safety reporting chain of command. Long term

corrective actions included developing and implementing new procedures, enhancing existing procedures, retraining the appropriate staff, hiring an additional medical physicist, reviewing past treatments to verify that none of them constituted a medical event, and implementing external reviews of radiation safety operations and safety culture. Additional corrective actions are detailed in the licensee's letter dated July 12, 2012.

By not taking sufficient action after the first medical event to prevent repeating the same failures the next day for the third treatment fraction, the second medical event occurred involving the same patient. Therefore, in accordance with Section 3.6 of the NRC Enforcement Policy, "Use of Discretion in Determining the Amount of a Civil Penalty," the NRC is exercising enforcement discretion to double the base civil penalty based on your poor performance in preventing the second medical event. As a result, the NRC is proposing a civil penalty of \$11,200, twice the base civil penalty.

Therefore, to emphasize the importance of taking adequate steps to identify the overall problem requiring corrective action, and because of the licensee's particularly poor performance, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$11,200 for the Severity Level II violation. In addition, issuance of this Notice 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 prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in NRC Inspection Report 030-11252/2012-001 and your letters dated January 24 (ML12121A689), February 8 (ML12046A882), March 22 (ML12104A081), April 12 (ML12104A107), and July 12, 2012 (ML12200A299). 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.

Independent of a response to the abovementioned Notice, 45 CFR Part 61, "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners," requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services' (HHS) Healthcare Integrity and Protection Data Bank. Since the HHS Databank requires information that the NRC does not normally collect, you are required to submit the following information: Federal Employer Identification Number (FEIN) or Social Security Number (when it is used as a Taxpayer Identification Number (TIN)); the National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); the type of organization; the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held. This information should be provided on a separate sheet of paper since it will not be publicly released. This enforcement action will not be closed until this information is received by the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738.

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 to the Notice, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management 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/reading-rm/doc-collections/enforcement/actions/>.

Should you have any questions concerning this letter or the enclosed Notice, please contact Mr. Michael Vasquez, Chief, Nuclear Materials Safety Branch A, at 817-200-1130.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket: 030-11252
License: 40-16571-01

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods

cc w/enclosure 1:
Robert Stahl, Administrator
Office of Health Care Facilities
Licensure & Certification
Systems Development & Regulations
615 East 4th Street
Pierre, SD 57501-1700

Internal distribution:

RidsSecyMailCenter Resource	RidsOcaMailCenter Resource	
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RidsRgn1MailCenter Resource	RidsRgn3MailCenter Resource	
Elmo.Collins@nrc.gov ;	Heather.Gepford@nrc.gov ;	Roy.Zimmerman@nrc.gov
Art.Howell@nrc.gov ;	Rachel.Browder@nrc.gov ;	Nick.Hilton@nrc.gov ;
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Michael.Vasquez@nrc.gov ;	Marisa.Herrera@nrc.gov ;	Kerstun.Day@nrc.gov ;
Jack.Whitten@nrc.gov ;	Victor.Dricks@nrc.gov ;	Lauren.Casey@nrc.gov ;
Blair.Spitzberg@nrc.gov ;	Lara.Uselding@nrc.gov ;	Carolyn.Faria-Ocasio@nrc.gov ;
Randy.Erickson@nrc.gov ;		Michele.Burgess@nrc.gov ;
Denise.Freeman@nrc.gov ;	Christian.Einberg@nrc.gov ;	Duane.White@nrc.gov ;
Sue.Trifiletti@nrc.gov ;	James.Thompson@nrc.gov	RobertoJ.Torres@nrc.gov
Jason.Razo@nrc.gov	Cayetano.Santos@nrc.gov	Michael.Clark@nrc.gov

Hard copy:

RIV Materials Docket File
 DNMS Secretarial File

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ADAMS		<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> SUNSI Review Complete	Reviewer Initials: JMR
<input checked="" type="checkbox"/> Publicly Available		<input type="checkbox"/> Non-publicly Available		<input type="checkbox"/> Sensitive	<input checked="" type="checkbox"/> Non-sensitive
RIV:DNMS/NMSB-A	C:NMSB-A	ES:ACES	RC	C:ACES	
JLThompson;dlf	GMVasquez	MCMaier	KSFuller	HJGepford	
<i>/RA/</i>	<i>/RA/</i>	<i>/RA/</i>	<i>/RA/ w/edits</i>	<i>/RA/ RSB for</i>	
08/ 09 /12	08 / 10 /12	08/27/12	08/28/12	08/29/12	
D:DNMS	DRA	FSME	OGC	OE	
AVegel	ATHowell	MBurgess	MClark	NHilton	
<i>/RA/ VHC for</i>	<i>/RA/</i>	<i>/RA/ E</i>	<i>/RA/ E</i>	<i>/RA/ E</i>	
08/29/12	08/29/12	09/20/12	09/20/12	09/21/12	
RA					
EECollins					
<i>/RA/</i>					
10/3/12					

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Avera McKennan Hospital
Sioux Falls, South Dakota

Docket: 030-11252
License: 40-16571-01
EA-12-090

During an NRC special inspection conducted from January 30 through February 2, 2012, at your facility in Sioux Falls, South Dakota, with continued in-office review through June 13, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees shall develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures required by 10 CFR 35.41(a) must meet the minimum requirements described in 10 CFR 35.41(b).

Contrary to the above, as of January 17, 2012, the licensee failed, for any administration requiring a written directive, to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the procedures in Radiation Oncology related to high dose-rate remote afterloader treatments failed to meet the following minimum requirements described in 10 CFR 35.41(b): (1) verify that the administration was in accordance with the treatment plan and written directive (10 CFR 35.41(b)(2)); (2) check both manual and computer-generated dose calculations (10 CFR 35.41(b)(3)); and (3) verify that any computer-generated dose calculations were correctly transferred into the consoles of therapeutic medical units (10 CFR 35.41(b)(4)).

This is a Severity Level II violation (Section 6.3).
Civil Penalty - \$11,200 (EA-12-090)

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 was achieved is already adequately addressed on the docket in NRC Special Inspection Report 030-11252/2012-001 (ML12166A427), and your letters dated January 24 (ML12121A689), February 8 (ML12046A882), March 22 (ML12104A081), April 12, (ML12104A107), and July 12, 2012 (ML12200A299). However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation under 10 CFR 2.201. In that case, or if you choose to respond, clearly mark your response as "A Reply to a Notice of Violation; EA-12-090," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region IV. The licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement,

ENCLOSURE 1

U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to a Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Mr. Roy Zimmerman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV.

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 Agencywide Documents Access and Management System (ADAMS). To the extent possible, it should not include any personal privacy, or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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).

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 3rd day of October 2012