



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

May 25, 2006

Docket No. 03001325
03035985

License No. 08-03604-03
08-03604-05

EA No. 05-212
06-123

Jeffrey A. Matton
Vice President for Professional Services
Washington Hospital Center
110 Irving Street, N.W.
Washington, DC 20010-2975

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION

Dear Mr. Matton:

This refers to the letter, dated April 19, 2006, submitted by your Radiation Safety Officer (RSO), Dr. Shashadhar Mohapatra, in response to our March 22, 2006, letter and the attached Notice of Violation with three cited Severity Level IV violations. The violations involved: (A) failure to apply for and receive an NRC license amendment prior to permitting a medical physicist to work under your limited scope license for gamma stereotactic radiosurgery (GSR), as required by 10 CFR 35.13(b); (B) failure to collect and document sufficient information to show that the aforementioned medical physicist met the training, experience, and recentness of training criteria established in 10 CFR Part 35 prior to permitting him to work under your broad scope license for high dose-rate remote afterloader activities; and (C) failure to measure timer linearity over the full range of use of the GSR device, as required by 10 CFR 35.635(b).

In your response, you acknowledged that the three violations occurred, however, you contended that the violations were of very low significance and met the criteria for a non-cited violation (NCV). Therefore, you requested that the Notice of Violation be rescinded and the violations be dispositioned as NCVs.

We have reviewed the basis for your request to disposition the three violations contained in our letter dated March 22, 2006, and the results of our review indicate the following:

1. With respect to the first violation, involving the failure to apply for and receive an NRC license amendment prior to permitting a medical physicist to work under your limited scope license for GSR, as required by 10 CFR 35.13(b), you contend that NRC, through e-mail and verbal conversations agreed that a license amendment to add an Authorized Medical Physicist (AMP) to the GSR license was not required, and, therefore, no violation occurred. In addition, you assert that if NRC decides to issue a violation, it should be disposed of as non-cited, because you did not have the opportunity to identify the violation and because you corrected the violation immediately. The NRC has evaluated your response and maintains that NRC regulations in 10 CFR 35.13(b) are clear that licensees who hold an NRC limited scope

license (e.g., your GSR license) must apply for and receive a license amendment before it permits anyone to work as an AMP, except as allowed by 10 CFR 35.961(a) or (b). The guidance provided to the staff of WHC by NRC staff via email dated November 12, 2003, confirmed the requirements of Part 35. We are unable to confirm your assertion that you had verbal concurrence from NRC staff to allow approval, without a license amendment, of a medical physicist who did not meet the requirements in 10 CFR 35.961(a) or (b). In the event you had received such concurrence, please note that 10 CFR 30.5 states that binding interpretations will either be specifically authorized by the Commission in writing or provided via a written interpretation by the General Counsel. Since (1) a binding interpretation does not exist for this issue; and (2) you allowed internal approval of the medical physicist, when an amendment was required, the NRC maintains that the violation occurred as stated in the Notice. In addition, since you did not identify the violation, an NCV is not warranted. With regard to your statement that you did not have the opportunity to identify the violation, we assert that NRC regulations and guidance are readily available and are clear on this issue.

2. With respect to the second violation, involving the failure to collect and document sufficient information to show that the aforementioned medical physicist met the training, experience, and recentness of training criteria established in 10 CFR Part 35 prior to permitting him to work under your broad scope license for high dose-rate remote afterloader activities, you acknowledged that appropriate documentation was not collected and maintained to approve the medical physicist. In addition, you agreed that WHC did not identify the violation, but assert that since the violation was of such low safety significance “the NRC should exercise its discretion and dispose of this violation as an NCV.” The NRC has evaluated your response and maintains that the violation occurred as stated in the Notice. This violation is a concern to the NRC because (1) the information your RSO discussed with your Radiation Safety Committee (RSC) did not contain all of the documentation of the training and experience required by Part 35 for authorization of an AMP, (2) your RSC failed to identify the missing documentation of experience and authorized the individual as an AMP, and (3) similar omissions of required documentation during the qualification review process could potentially lead to the authorization of an unqualified individual, and, therefore, directly impact public health and safety. Additionally, since the violation was identified by NRC staff, the NRC maintains that issuance of an NCV is not warranted
3. With respect to the third violation, involving the failure to measure timer linearity over the full range of use of the GSR device, as required by 10 CFR 35.635(b), you agree that WHC did not identify the violation, but assert that since the violation was of such low safety significance that “the NRC should exercise its discretion and dispose of this violation as an NCV.” The NRC has evaluated your response and agrees, in this instance, that your failure to determine GSR timer linearity over the full range of use as required by 10 CFR 35.635(b) did not result in patient harm and therefore did not

have a safety impact. Nonetheless, the operation of the GSR unit is dependant on the proper functioning of the timer and therefore potentially has a direct safety impact to patients. Accordingly, we assert that this violation is more than minor. Additionally, since the violation was identified by NRC staff, the NRC maintains that issuance of an NCV is not warranted.

The NRC has concluded that the corrective and preventative actions documented in your response adequately address the provisions of 10 CFR 2.201, and no further correspondence with us on this issue is needed. Your corrective and preventative actions will be examined during a future inspection of your licensed program.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Thank you for your cooperation.

Sincerely,

Original signed by George Pangburn

George Pangburn, Director
Division of Nuclear Materials Safety

cc:
Shashadhar Mohapatra, Ph.D., Radiation Safety Officer
District of Columbia

DISTRIBUTION w/encl:

ADAMS (PARS)
 SECY
 CA
 OEMAIL
 L Reyes, EDO
 M Virgilio, DEDMRS
 M Johnson, OE
 B Jones, OGC
 L Chandler, OGC
 J Strosnider, NMSS
 C Miller, NMSS
 C Miller, OEDO
 G Morell, NMSS
 Enforcement Coordinators
 RII, RIII, RIV
 S Figueroa, OE
 M Elwood, OGC

S Gagner, OPA
 H Bell, OIG
 J Schlueter, STP
 G Caputo, OI
 L Tremper, OCFO
 D Screnci, PAO-RI
 N Sheehan, PAO-RI
 G Pangburn, RI
 F Costello, RI
 P Henderson
 K Farrar, RI
 D Holody, RI
 J Wray, RI
 R. Summers, RI
 C O'Daniell, RI
 S Villar, RI
 Region I OE Files (with concurrences)

DOCUMENT NAME: E:\Filenet\ML061450364.wpd

SISP Review Complete: RRagland

After declaring this document "An Official Agency Record" it will be 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	<input type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	ORA/RI	<input type="checkbox"/>	RC/RI	<input type="checkbox"/>
NAME	Planzisera		GPangburn		DHolody JRW3		KFarrar	
DATE	5/8/06		5/12/06		5/15/06		5/16/06	
OFFICE	NMSS	<input type="checkbox"/>	OE	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
NAME	GMorrell per email from		SMerchant					
DATE	Smerchant 5/23/06		per email 5/23/06					