

September 20, 2005  
EN 05-041

OFFICE OF ENFORCEMENT  
NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

Licensee: St. Joseph Regional Medical Center (EA 05-128)  
South Bend, IN 46617-1935  
Docket No. 030-13685

Subject: PROPOSED IMPOSITION OF CIVIL PENALTY- \$19,200

This is to inform the Commission that a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$19,200 will be issued on or about September 23, 2005, to St. Joseph Regional Medical Center for circumstances surrounding medical events involving three patients who received unintended radiation doses to the skin of their thighs during vaginal brachytherapy treatments that were conducted between February 23 and March 22, 2004. Based on an NRC medical consultant's evaluation, three patients received unintended doses of radiation to their thighs in the range of 1,500 cGy to 2,200 cGy. These events were caused by the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive and the failure to instruct a medical physicist on various facets of the licensee's brachytherapy program. Because these violations directly contributed to the medical events and resulted in significant health consequences for the three patients, each event is separately categorized as a Severity Level II problem and assessed a base civil penalty of \$4,800 in accordance with the NRC Enforcement Policy. A separate Severity Level II violation is associated with the licensee's initial failure to report the medical events until approximately 1 year later. This was also assessed a base civil penalty. In addition, a Severity Level IV violation will be issued for the same underlying problem in which two additional patients may have received unintended doses of radiation that did not exceed 300 cGy.

The NRC considered whether credit was warranted for Identification and Corrective Action for the Severity Level II problem or violation in accordance with the civil penalty assessment process in Section VI.C.2 of the NRC Enforcement Policy. Identification credit was not warranted since the violations were identified by the NRC. Credit was warranted for corrective action based on the licensee's extensive corrective actions which included: revision and implementation of policies and procedures; clarification of written directive requirements; completion of staff training; revision of the policy and duties of the radiation safety committee members; development of an annual review of medical physicist competency; appointment of a new Radiation Safety Officer; and recruitment of an in-house medical physicist. Therefore, in order to emphasize the significance of these violations, the NRC proposes to impose a civil penalty of \$19,200.

It should be noted that the licensee has not been specifically informed of the enforcement action. The schedule of issuance and notification is:

Mailing of Notice	September 23, 2005
Telephone Notification of Licensee	September 23, 2005

The State of Indiana will be notified.

The licensee has thirty days from the date of the Notice in which to respond. Following NRC evaluation of the response, the civil penalty may be remitted, mitigated, or imposed by Order.

Contacts: Sally Merchant, OE, 415-2747; Chris Nolan, OE, 415-2741

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SMerchant

C. Nolan

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**PRELIMINARY INFORMATION - NOT FOR PUBLIC DISCLOSURE UNTIL  
VERIFICATION THAT LICENSEE HAS RECEIVED ACTION**