

December 10, 1996

U.S. Nuclear Regulatory Commission
NRC Document Control Desk
Washington, D.C. 20555-001

30-2006

SUBJECT: Potential Reportable Item (10 CFR Part 21.21)
NRC License No. 21-01333-01

A potential reportable item, as regulated by 10 CFR Part 21.21, "Notification of failure to comply or existence of a defect in its evaluation," was identified on November 29, 1996 when our Nucletron HDR Microselectron malfunctioned as follows. On Friday, November 29, 1996, there were no problems experienced during the daily quality assurance tests performed prior to patient treatment. On Friday afternoon, a patient with a carcinoma of the prostate was treated with the HDR-RAL (high dose rate remote afterloading device) unit with Ir-192 (4.2 Curie). Thirteen needles were placed into the treatment site (i.e., the prostate) and the position was verified to be in accordance with the treatment plan. The treatment plan specified dwell times for each of five dwell positions within each needle. The treatment parameters were verified in accordance with our Quality Management Program and the treatment commenced at 2:44 p.m. The source progressed as programmed from dwell position nine through dwell position one in the first twelve needles. At 2:59 p.m., after the source had progressed through two of the five programmed positions for the last needle (i.e., dwells nine and seven in needle thirteen), the dosimetrist bumped the tabletop on which the HDR-RAL control unit is placed, and this caused the control unit to temporarily lose communication with the HDR-RAL device delivering the treatment to the patient. The physicist was watching the control unit display at the time of the event and observed that the source had at the moment completed the programmed dwell time for position seven of needle thirteen. At the same time the radiation source retracted from the patient into the safe as verified audibly on the intercom and visually on the video monitor (i.e., the gold hand crank attached to the drive motor was observed as it rotated and retracted the source into the safe). The physicist immediately verified that the source was fully retracted into the safe via the radiation monitor.

The control unit regained communication and began printing previously printed information. The physicist then turned the control unit key from the "treatment" position to the "prepare" position. A patient survey was completed which verified that the source had retracted. The physicist reviewed the treatment tape which documented the dwell time treated for dwell positions nine and seven in needle thirteen. The dwell time treated, however, for position five (i.e., when the event occurred) was not printed on the treatment tape. Because the physicist was observing the HDR-RAL control console at the time of the event, she knew that dwell position five had not received any of the programmed dwell treatment time within one second.

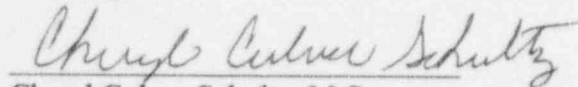
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CORRECTIVE ACTIONS: Full communication was restored between the control unit and the treatment unit and the physician authorized user decided to complete the treatment by reprogramming the console to treat the last three dwell positions in needle thirteen (dwell positions five, three and one). Treatment was completed in accordance with the written directive. Nucleotron service was contacted immediately. On Sunday, December 1, 1996, the authorized Nucleotron service engineer replaced the control unit microcomputer board and the control unit power supply. The communication between the control unit and the treatment unit was thoroughly tested and functioning properly. Prior to patient treatment, the physicist tested and verified the source position, accuracy and linearity. All of the daily quality assurance checks were completed without a problem.

This incident would not have caused a recordable event or misadministration since the source immediately withdrew into the safe. The treatment console, however, did not print out the time parameter for the dwell position when the event occurred. If the physicist had not been watching the control unit at the time of the event, then it would not have been possible to determine how long the source had remained at dwell position five of the thirteenth needle. The service engineer for Nucleotron, however, thought that this time parameter may have printed out after the event, if the treatment console had not been turned from the "treatment" position to the "prepare" position. A copy of the treatment tape printout is included in the attachment.

Sincerely,



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