

*Summary of Licensee Response to Example A.3 of the Violation*

The Licensee states that it denies this example. The Licensee states that, contrary to the NRC findings, checks were performed and an entire log indicating that certain checks were performed does exist. In its letter dated December 1, 1994, the Licensee provided numerous log entries to show that checks were performed.

*NRC Evaluation of Licensee's Response to Example A.3 of the Violation*

The NRC staff has reviewed the log entries provided by the Licensee on December 1, 1994. Based on those records, which were not provided during the inspection or the transcribed enforcement conference, the NRC staff is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

*Summary of Licensee Response to Example A.4 of the Violation*

The Licensee denies the example and asserts that relevant personnel attended Omnitron training where dry runs were performed and emergency situations and procedures were taught and discussed. The Licensee believes that, in any event, this could constitute a Severity Level IV violation.

*NRC Evaluation of Licensee's Response to Example A.4 of the Violation*

While Omnitron training may have covered emergency situations, License Condition 14 specifically requires that each operator/user of the HDR individually demonstrate emergency routine competence during "dry run" emergencies using several failure modes for each operator. At the transcribed enforcement conference, the Medical Director, recalling the portion of the Omnitron training that pertained to emergency situations, stated, "[t]o the best of my recollection, I believe they went through some of the descriptive terms on how to re crank the machine manually, and I believe they showed us the knob. But I cannot say with any degree of recollection that we actually went through it." As noted in the inspection report, the dosimetrist stated to inspectors that she had not performed "dry run" emergencies using several failure modes. Therefore, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

*Summary of Licensee Response to Example A.5 of the Violation*

The Licensee admits this example of the violation, but states its belief that this would constitute a Severity Level IV violation.

*NRC Evaluation of Licensee's Response to Example A.5 of the Violation*

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

*Summary of Licensee Response to Example B of the Violation*

The Licensee denies this example. The Licensee states that failure to answer all questions posed by the inspector does not necessarily constitute evidence that employees were not adequately trained in accordance with the commitments in the application or in the regulations. The Licensee believes that at all times personnel were trained as required under the license and under the applicable regulations. The Licensee states that 10 CFR 19.12 only requires that personnel be trained "commensurate with potential radiological health protection problems in the restricted area." The Licensee also states that "the NRC did not allege that the dosimetrist did not know how to operate a hand held survey meter or that she was not trained in its operation." The Licensee asserts that the dosimetrist was trained pursuant to license requirements. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

*NRC Evaluation of Licensee's Response to Example B of the Violation*

As documented in the inspection report, the dosimetrist was asked to demonstrate the operation and use of the radiation survey meter. The dosimetrist incorrectly set the instrument response dial to the X1000 scale, stating that this was the instrument's lowest strength scale. The inspectors asked the dosimetrist to repeat this demonstration and explanation a second time and the dosimetrist produced the same result. The dosimetrist is the individual who operated the HDR unit at Marlton. When the inspectors asked the dosimetrist to explain the meaning of the "error code" and "error class" messages on a printout of a treatment record, the dosimetrist stated that she did not know the meaning of the error messages.

The NRC staff finds that the dosimetrist's lack of understanding of the differences between the highest setting on the meter and the lowest setting on the meter, as well as the lack of understanding concerning response to HDR error messages are clear evidence that adequate training was not provided.

10 CFR 19.12 also requires that all individuals working in or frequenting any portion of a restricted area shall be instructed in precautions or procedures to minimize exposure, and in the purposes and function of protective devices employed. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. The dosimetrist operated the HDR. In an emergency situation, the dosimetrist's duties could involve use of a survey meter to determine the status and location of the source in the restricted area as a means of protecting herself as well as other employees and patients. The Licensee clearly recognized that emergency situations could arise because it discussed "dry run" emergency procedures

in its license application. In addition, since the dosimetrist's duties included operation of the HDR, this individual should have been knowledgeable on the meaning of error messages and how to respond to error messages generated by the HDR unit. Error messages could indicate hazardous conditions in the restricted area. Therefore, this individual was required by 10 CFR 19.12 to be trained by the Licensee on the meaning of the error messages, how to respond to error messages, and the use of a hand-held survey meter. Based on the above, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

*Summary of Licensee Response to Example C of the Violation*

The Licensee states in its response that it admits in part and denies in part this example. The Licensee asserts that it did record certain changes and may not have recorded others. The Licensee further asserts that, in this case, there was no potential or actual impact on health and safety. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

*NRC Evaluation of Licensee's Response to Example C of the Violation*

10 CFR 35.31 authorizes medical use licensees to make minor changes in radiation safety procedures that are not potentially important to safety. 10 CFR 35.31(b) requires that if these changes (ministerial changes) are made, the licensee must maintain a record as specified in the regulation. There is no exception granted to the Licensee to only record certain changes. Since the Licensee did not maintain a record of some changes, the NRC concludes that this example of the violation occurred as stated in the Notice. The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

*Summary of Licensee Response to Example D of the Violation*

The Licensee states in its response that it denies this example. The Licensee asserts that it had a written quality management program (QMP) which was in effect at the relevant times. In addition, the Licensee states that it has modified its quality management plan pursuant to completion of a review of its HDR program, and that the modified plan has been submitted to the NRC.

*NRC Evaluation of Licensee's Response to Example D of the Violation*

The requirement is that the Licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The inspection report indicates that inspectors did find a copy of "Quality Management of Brachytherapy Patients High Dose Rate Techniques" authorized by David Cunningham of Oncology Services Corporation and dated January 16, 1992. This