Although knowledge on the part of the AU that the wall mounted radiation monitor had been flashing is not necessary to prove the violation, the fact that the AU was aware that the wall mounted radiation monitor was flashing as he entered the treatment room is corroborated by his testimony, as well as the testimony of others, in transcribed interviews. Additionally, the transcribed interviews of the AU consistently show that, while he was in the treatment room, he was aware that: (1) The wall mounted radiation monitor had been flashing; and (2) the Omnitron console showed that the source was safely retracted.

NRC agrees that the Omnitron source broke off and was not retracted, that this was neither expected nor intended by the Licensee, and that the Licensee could not have prevented the break. However, that does not change the fact that the survey required by 10 CFR 20.201 was not performed, which is a matter that was within the Licensee's control. Given the conflicting information from the flashing wall mounted radiation monitor and the Omnitron control panel, such a survey was reasonable under the circumstances to evaluate the extent of the radiation hazards that were present. Since such a survey was not performed, the NRC concludes that Violation I.A occurred as stated in the Notice. The issue of the severity level of the violation is addressed in the evaluation of the Licensee's Response to Violation I.B, below.

Summary of Licensee's Response to Violation I.B

The Licensee denies Violation I.B; incorporates its response to Violation I.A, summarized above; and asserts that Violation I.B would be a Severity Level IV violation. The Licensee states that the wall mounted radiation monitor should have continued to alarm, and that if the monitor had done so, the technologist and authorized user would have acted accordingly.

NRC Evaluation of Licensee's Response to Violation I.B

Licensee employees entered the treatment room while the wall mounted radiation monitor was alarming, indicating a non-safe condition, and they did so without a portable survey meter or audible dosimeter. If the employees believed that the wall mounted radiation monitor was functioning properly, they should not have entered the treatment room while it was alarming, which is a violation of License Condition 17. If the employees discounted the alarm because they believed that the wall mounted radiation monitor was not functioning properly (i.e., spuriously alarming), they should not have entered the treatment room without a portable survey meter or audible dosimeter, which is also a violation of License Condition 17.

Moreover, the requirements of License Condition 17 as cited in Violation I.B were being violated even before the authorized user entered the treatment room. The transcribed interviews clearly show that the monitor was alarming when the technologists entered the treatment room. The violation occurred upon entry. Thus, whether the monitor should have continued to alarm after the technologist entered the treatment room and manipulated its plug is not relevant to the existence of the violation. Accordingly, the NRC concludes that Violation I.B occurred as stated in the Notice.

Among other things, Violations I.A and I.B were classified in the aggregate as a Severity Level I problem in accordance with Supplements IV and VI of the NRC Enforcement Policy because: (1) Conducting the survey and complying with the requirements of License Condition 17 regarding the wall mounted radiation monitor, and the use of a portable survey meter or audible dosimeter in the event of a failure of the wall mounted radiation monitor, constitute a system designed to prevent or mitigate a serious safety event, and in this case, the system was not operable when actually required to perform; and (2) the violations resulted in acute radiation exposure and subsequent death of a patient. See Enforcement Policy (1993), Supplement IV, Example A.2; and Supplement VI, Examples A.2 and A.4.

Restatement of Violations in Section II of the Notice

II.A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the Licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, from November 16, 1992 to December 1, 1992, licensed material consisting of Curie quantities of iridium-192 was located at a nursing home, a waste disposal facility, and several vehicles, which are unrestricted areas, and the licensed material was not secured against unauthorized removal nor was it under the constant surveillance and immediate control of the Licensee.

B. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no Licensee shall possess, use, or transfer licensed material in such a manner as to create radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, from November 16, 1992 to December 1, 1992, the Licensee allowed the creation of radiation levels in unrestricted areas. such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, the Licensee allowed the creation of radiation levels of approximately 2000 millirem per hour at a distance of one meter in unrestricted areas, specifically a nursing home, a waste disposal facility, and several vehicles.

These violations represent a Severity Level I problem (Supplement IV) Civil Penalty—\$100,000.

Summary of Licensee Response to Violations II.A and II.B

The Licensee denies Violations II.A and II.B and incorporates by reference its response to the violations in Section I. The Licensee contends that the source was lost, not possessed, used, transferred or stored. According to the Licensee, loss is an accidental act, while, as used in NRC regulations, possession, use, transfer and storage are deliberate acts. The Licensee asserts that the cited violations would have required knowledge of attending personnel that the source was still in the patient, but since they did not know the source was still inside the patient, the Licensee did not possess, use, transfer or store material in violation of any regulations.

NRC Evaluation of Licensee's Response to Violations II.A and II.B

The Notice does not assert, expressly or otherwise, that the violations were knowing or deliberate. Neither 10 CFR § 20.207 nor § 20.105 require a knowing failure to maintain control of licensed material, or knowing exposure of individuals to radiation, in order to establish a violation. Under the regulations in 10 CFR part 20, licensees are strictly held accountable for loss of