

production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, on November 16, 1992, the Licensee did not make a survey necessary to comply with the requirements of 10 CFR 20.101 which limits radiation exposure to individuals in restricted areas, and 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, although the room radiation monitor in the treatment room (restricted area) at the Indiana Regional Cancer Center (IRCC), flashed the red alarm signal even after the console of the High Dose Rate (HDR) afterloader unit showed that a 4.2 Curie iridium-192 source was safely retracted (because the source had broken off inside the patient), a radiation survey was not performed to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor.

B. Condition 17 of License No. 37-28540-01, Amendment No. 3 dated August 19, 1992, requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated June 1, 1990, and the letter dated August 2, 1990.

Item 9.C.3 of the application dated June 1, 1990, requires, in part, that a radiation monitor (PrimAlert or equivalent) be mounted on the wall [in the HDR afterloader treatment room] and will remain in place as a means of verifying a source "safe" or "out" condition.

Item 10.15.A.3 of the application dated June 1, 1990, requires, in part, that all attending personnel must remain in the control area during actual treatment and may not re-enter the treatment room until the room radiation detector (PrimAlert) indicates a safe condition prevails.

Item 6 of the letter dated August 2, 1990, states that failure of the radiation monitor will result in termination of the treatment until the monitor is replaced or repaired and, in the event of failure of the room monitor, no personnel will enter the room without a portable survey meter or audible dosimeter.

Contrary to the above, on November 16, 1992, during a patient treatment utilizing an iridium-192 source in a HDR afterloader, at the IRCC, when the wall-mounted radiation monitor flashed the red alarm signal to indicate a source "out" condition, a physician authorized user, who had been informed that the red alarm signal was flashing, entered the treatment room without a portable

survey meter or audible dosimeter; and, at some point during the event, a Licensee technologist entered the treatment room and unplugged and replugged the power supply of the room radiation monitor to reset the alarm.

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

#### *Summary of Licensee's Response to Violation I.A*

The Licensee in its responses, denies Violation I.A and states that the treatment room at the Indiana Regional Cancer Center was surveyed with what the Licensee terms "a wall mounted survey instrument ("WMSI")", the WMSI did not flash red in the presence of the authorized user, and the WMSI stopped flashing when the electrical connection was touched. The Licensee further asserts that the authorized user was not aware, prior to entering the treatment room, that the WMSI had flashed. The Licensee also asserts that all output on the Omnitron unit and console indicated that the source was parked and safe; no alarm went off on the Omnitron unit; and all personnel acted in accordance with what the Licensee terms its "NRC approved Omnitron training." The Licensee states that the conduct of the authorized user and the Licensee was reasonable at all times and in conformity with NRC regulations.

The Licensee also states that the Omnitron machine failed; that failure was neither expected nor intended; and that the Licensee could not have prevented the failure. The Licensee also notes that it believes the NRC was in a much better position to understand the need for adequate surveys, yet the NRC license application reviewer did not find it necessary to require, or even request, the Licensee modify its license application or procedure to include a patient survey with a hand held survey meter after each treatment. The Licensee states that it believes that at all times it followed the applicable regulations, and that it was the victim of a machine failure and inadequate and/or outdated regulations. The Licensee further states that there was no intent to violate any regulations and that personnel were not reckless. The Licensee states that since the WMSI was not flashing when the authorized user was in the treatment room, to expect the authorized user to act other than as he did is not rational under the existing circumstances. The Licensee believes that, in any event, this violation would be classified at Severity Level IV.

#### *NRC Evaluation of Licensee's Response to Violation I.A*

The specific issue addressed in Violation I.A is whether the Licensee performed a survey as required by 10 CFR 20.101 to confirm or discount the presence of a radiation hazard in the room or the patient as indicated by the alarming room monitor. The fact that the wall mounted radiation monitor flashed the red alarm signal even though the Omnitron console showed that the source was safely retracted is the condition that triggered the requirement to conduct a survey pursuant to § 20.201. Thus, the Licensee cannot point to the same wall mounted radiation monitor as fulfilling the requirement to conduct the survey pursuant to § 20.201. Rather, the Licensee was required under those circumstances, pursuant to § 20.201, to perform an independent survey, such as by using a hand held radiation survey instrument, to determine which indicator was correct—the wall mounted radiation monitor, or the Omnitron console. The Licensee failed to do this and chose instead to discount the alarm from the wall mounted radiation monitor and to rely on the Omnitron console indicator.

As to the Licensee's statement that the regulations are inadequate or outdated, the Licensee does not identify any particular regulation. However, only 10 CFR 20.201 is cited in Violation I.A. An extensive revision of 10 CFR Part 20 became effective January 1, 1994, and the survey requirement of 10 CFR 20.201 is now codified at 10 CFR 20.1501. The language of the specific requirement has been changed only slightly. The survey requirement of 10 CFR 20.201 is not outdated or inadequate. It would have been a simple matter for the Licensee to comply with the requirement using the hand held survey instrument that the Licensee had on hand, which is a basic radiation protection practice.

Even before the authorized user (AU) arrived at the treatment room, Licensee technologists noticed that the wall mounted radiation monitor was flashing, knew that the Omnitron console indicated that the source was retracted safely, and yet they were present in the treatment room without having performed the survey required pursuant to § 20.201. At this point, such a survey was necessary to comply with the requirements of 10 CFR 20.101, which limits exposure to individuals in restricted areas. Thus, Violation I.A was occurring even before the AU entered the room.