

radioactive material and for radiation levels in unrestricted areas caused by such loss. As a result of the Licensee's use of the source on November 16, 1992, the source escaped the Licensee's control and was transferred to the nursing home and, subsequently, to other unrestricted areas, where it created radiation levels far in excess of the allowable limits. Therefore, the NRC concludes that Violations II.A and II.B occurred as stated in the Notice.

*Restatement of Violations in Section III of the Notice*

III.A. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

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.

Item 8 of the application dated June 1, 1990, requires, in part, that training for HDR device operators will include emergency training where the device operator will demonstrate emergency routine competence during a "dry run" emergency of the source not retracting.

Contrary to the above, individuals who were working in the HDR afterloader treatment room, a restricted area, at three of the Licensee's six facilities in Pennsylvania, had not been adequately instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and the conditions of the license, as evidenced by the following examples:

1. As of December 18, 1992, technologists working in a restricted area at the Indiana facility were not adequately instructed in how to use a survey meter, the meaning of a high radiation area, the methods of performing HDR afterloader door interlock checks, the significance of the

alarm setpoint (the preset value) of the wall-mounted radiation monitor, the meaning of HDR afterloader error messages, the activity of the sources contained in the HDR unit and their potential radioactive hazard, or the corporate policy that requires the staff to survey each patient treated with the HDR afterloader unit with a portable survey meter before the patient's release, and in addition, individuals who operated the HDR device had not performed a "dry run" emergency; and

2. As of December 8, 1992, Licensee personnel working in restricted areas at the Exton and Lehighton facilities had not been instructed in the applicable provisions of the Commission's regulations and the NRC license, and individuals who operated the HDR device had not performed a "dry run" emergency of the source not retracting.

B. 10 CFR 35.25(a)(1) requires, in part, that a Licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the Licensee's written quality management program.

Contrary to the above, as of December 8, 1992, the Licensee did not instruct personnel who used iridium-192 under the supervision of an authorized user at the Exton facility in the Licensee's written quality management program.

C. 10 CFR 20.202(a) (1) and (3) requires, in part, that: Each Licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a); and each Licensee supply appropriate personnel monitoring equipment to, and require the use of, such equipment by each individual who enters a high radiation area.

Contrary to the above,

1. On November 16, 1992, during a treatment of a patient with iridium-192 in a HDR afterloader unit, the physician authorized user at the Indiana facility entered the treatment room, a restricted area, and, although the wall-mounted radiation monitor had flashed the red alarm signal to indicate the presence of a radiation field, the authorized user did not wear his personal monitoring equipment; and,

2. On December 1, 1992, the authorized user at the Indiana facility, in efforts to retrieve the iridium-192 radioactive source, entered a high radiation area at the Browning-Ferris Industries waste facility in Carnegie,

Pennsylvania, and did not wear his personnel monitoring equipment.

D. Condition 17 of License No. 37-28540-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated June 1, 1990, and a letter dated August 16, 1991.

1. Item 10.2 of the application dated June 1, 1990, states that the Licensee will establish and implement the ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

Appendix G to Regulatory Guide 10.8, Revision 2, requires, in part, that the RSO [Radiation Safety Officer] be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

Contrary to the above, as of December 3, 1992, the RSO did not maintain close contact with all users and workers. For example, Medical Director/Authorized Users at the Indiana and Lehighton facilities were not aware of who the RSO was. Additionally, the RSO had not visited the Lehighton facility in the past 6-9 months.

2. Item No. 10.15.A.1 of the June 1, 1990, application requires that emergency procedures be conspicuously posted near the control console.

Contrary to the above, on December 8, 1992, the emergency procedures were not posted at the Exton facility.

3. Item No. 10.15.B.1 of the June 1, 1990, application requires that the calibration of the HDR afterloader source and device include a check of source travel time error and accuracy of the timing device.

Contrary to the above, as of December 8, 1992, the calibration of the HDR afterloader source and device at the Exton facility did not include a check of source travel time error and accuracy of the timing device.

4. Item No. 10.12 of the June 1, 1990, application requires that surveys of radiation levels in adjacent and control areas be performed at each source exchange and logged.

Contrary to the above, as of December 8, 1992, surveys of radiation levels in adjacent and control areas were not performed at each source exchange at the Exton facility.

5. The Licensee's letter dated August 16, 1991, requires, in part, that the key for the linear accelerator and the key for the HDR afterloader unit be on the same ring to prohibit the simultaneous activation of these units.

Contrary to the above, on December 8, 1992, the key for the linear accelerator and the key for the HDR afterloader unit