portion of a restricted area be instructed in the purposes and functions of protective devices employed, and in the appropriate response to warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

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.

Contrary to these requirements,

1. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the purposes and functions of protective devices employed. Specifically, the Licensee failed to instruct the dosimetrist in the proper use of the radiation survey meter. The dosimetrist, when questioned by the inspector on the operation and use of the survey meter, stated that the X1000 setting was the instrument's "lowest strength" scale. The X1000 setting is actually the highest scale setting on the instrument.

2. As of February 4, 1993, individuals working in or frequenting portions of a restricted area were not instructed in the appropriate response to a warning made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material. Specifically, the Licensee failed to adequately train the dosimetrist to identify and respond to HDR error messages.

When questioned by the inspector on February 4, 1993, the dosimetrist did not know the meaning of the error messages from a random printout of a treatment execution record, dated May 7, 1992, which contained several error messages.

C. 10 CFR 35.31(b) requires that a licensee that makes minor changes in radiation safety procedures, as permitted under 10 CFR 35.31(a), retain a record of each change until the license has been renewed or terminated. The record shall include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Contrary to this requirement, prior to February 2, 1993:

1. The Licensee made a minor change in its radiation safety procedures, as permitted under 10 CFR 35.31(a), by posting emergency procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reasons for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

2. The Licensee made a minor change in its radiation safety procedures, as permitted

under 10 CFR 35.31(a), by using HDR calibration procedures that differed from those procedures submitted to the NRC in support of the license application, and the Licensee did not retain a record of the change that included the effective date of the change, the reason for the change, a summary of the radiation matters that were considered before making the change, the signature of the RSO, and the signatures of the affected authorized users, and of management.

D. 10 CFR 35.32 requires, in part, that each licensee, as applicable, 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.

Contrary to this requirement, from March through December 1992, the Licensee engaged in licensed activities (namely, the administration of brachytherapy radiation doses using an iridium-192 source in an HDR unit) which required the establishment of a quality management program, and as of February 5, 1993, the Licensee had not established a written quality management program.

E. 10 CFR 35.51(a)(3) requires that the apparent exposure rate from a dedicated check source as determined at the time of calibration, be conspicuously noted on the instrument with the date of calibration.

Contrary to this requirement, as of February 4, 1993, the apparent exposure rate from a dedicated check source as determined at the time of calibration, was not conspicuously noted on the instrument with the date of calibration.

F. 10 CFR 19.11 (a) and (b) require, in part, that the Licensee post current copies of Part 19 and 20, and the license, or post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) also requires that the licensee post a Form NRC–3, "Notice to Employees."

Contary to this requirement, as of February 4, 1993, the Licensee did not post current copies of Parts 19 and 20, and the license, or a notice describing the documents and where they could be examined, and did not post a Form NRC-3.

G. 10 CFR 30.51(a) requires each licensee to keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to this requirement, as of February 4, 1993, the Licensee did not keep records showing the receipt, transfer, and disposal of byproduct material. Specifically, the Licensee did not maintain records of the source receipt and transfer for disposal.

This is a Severity Level II violation (Supplement VI).

Summary of Licensee's Response to Example A.1 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states that, although the RSO was not present in the room during the source exchange, the RSO or the physicist was physically present at the facility during the source exchanges, or readily available in case of an emergency, and thus the RSO was overseeing the source exchanges. The

Licensee believes that this was all that was intended by its license application, that the RSO may delegate duties, and that the physical presence of the RSO during a source exchange would violate ALARA principles. The Licensee believes that, in any event, this example would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.1 of the Violation

The Licensee's application is clear in requiring that all source exchanges be carried out by Omnitron Factory Personnel under the observation of the RSO. With proper planning and the application of common radiation protection methods, the RSO could observe source exchanges without violating ALARA principles. At the transcribed enforcement conference, the RSO confirmed that she observed the first source exchange but did not observe the three subsequent source exchanges. Since source exchanges occurred that were not under the observation of the RSO, 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.2 of the Violation

The Licensee admits this example in part and denies it in part, but does not state specifically what it admits or denies. The Licensee states its belief that surveys of radiation levels in adjacent areas and/or controlled areas were performed during the source exchanges which occurred on March 5, June 4, and September 16, 1992, by Omnitron for the Licensee's benefit. The Licensee, in its letter dated December 1, 1994, provided Omnitron's record of surveys conducted during the source exchange on December 9, 1992, as well as other records of surveys conducted on March 5, June 4, and September 16, 1992. The Licensee believes that, in any event, this would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Example A.2 of the Violation

Omnitron's record of surveys conducted on December 9, 1992 does not show that all adjacent areas were surveyed as required by License Condition 14. Regarding the records of other surveys that the Licensee submitted, the NRC inspection report indicates that the inspectors did see documentation of partial surveys for March 5, 1992, June 4, 1992, and September 16, 1992. With the exception of the survey record for December 17, 1992, the survey records that the Licensee submitted show that the surveys did not include all adjacent areas as required by the license condition. As noted in the inspection report, examples of adjacent areas that were not surveyed include a staff restroom, a utility room, the patient examination room, and the patient dressing room. 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.'