

Curies of iridium-192, a radioactive material, without a shipping paper.

3. 49 CFR 172.504 prescribes requirements for placarding vehicles used to transport hazardous materials. Specifically, Table 1 requires that the transport vehicle be placarded on each side and each end with a "RADIOACTIVE" placard when transporting packages bearing a "RADIOACTIVE YELLOW-III" label (footnote 4).

Contrary to the above, on December 1, 1992, the Licensee transported 3.7 Curies of iridium-192 outside the confines of its plant in a package with the required YELLOW-III label, and the transport vehicle was not placarded with a "RADIOACTIVE" placard.

These violations represent a Security Level II problem (Supplement IV, V and VI) Civil Penalty—\$80,000.

Summary of Licensee's Response to Violations III.A and III.B

The Licensee denies Violations III.A and III.B and states that at all times it adequately instructed all personnel in relevant areas consistent with 10 CFR 19.12, 10 CFR 35.25(a)(1), and the license, and that it would be incorrect for NRC to take the position that each and every individual must be knowledgeable about each and every regulation and/or license condition. The Licensee believes that, in any event, these violations would be classified at Severity Level III.

NRC Evaluation of Licensee Response to Violations III.A and III.B

The Licensee was not cited for failure to instruct each and every individual in every NRC requirement. 10 CFR 19.12 requires that training for workers be commensurate with potential radiological health protection problems in restricted areas. Additionally, training must fulfill specific regulations such as 10 CFR 35.25(a)(1), as well as specific commitments made by the Licensee and incorporated into the license by condition. Violations III.A and III.B were identified as a result of discussions between OSC personnel and NRC inspectors or investigators. NRC does not dispute that some training did occur. However, as documented in the inspection report, the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of Investigations (OI), the training that was given was not adequate to meet the requirements. The Licensee's general assertion that it complied with all requirements does not refute the fact that the specific subjects described in Violations III.A and III.B were not covered adequately in the training that

the Licensee gave to the personnel described in Violations III.A and III.B. Thus, the NRC concludes that the violations occurred as stated in the Notice.

The NRC did not categorize the individual violations and examples of violations in Section III of the Notice by severity level. Rather, the NRC considered the violations in the aggregate as a single problem categorized at Severity Level II. The Enforcement Policy defines a Severity Level II violation or problem as one of very significant concern. Clearly, this severity level is appropriate here because the number and nature of the violations represent a very significant corporate management breakdown in the control of licensed activities; and the lack of attention to, and understanding of, regulatory requirements on the part of Licensee management and its RSO contributed to the November 1992 event. The purpose of aggregating violations is to focus the Licensee's attention on the fundamental underlying causes for which enforcement action is warranted, and to reflect the fact that several violations with a common cause are more significant collectively than individually, and therefore, warrant a more substantial enforcement action. See Enforcement Policy, Section IV.A. In this case it was necessary to focus the Licensee's attention on the importance of meticulous oversight of the corporate radiation safety program, the lack of which was a common causative factor in the violations.

Summary of Licensee's Response to Violation III.C

The Licensee denies Example III.C.1 and states that it supplied and required the use of personnel monitoring equipment; however, the authorized user had no reason to believe that it was necessary to wear a film badge. The Licensee further incorporates by reference its response to Violations A and B in Section I of the Notice. The Licensee believes that, in any event, Example III.C.1 would constitute a Severity Level V violation. The Licensee admits Example III.C.2 but believes that it constitutes a Severity Level V violation.

NRC Evaluation of Licensee Response to Violation III.C

10 CFR 20.202(a)(1) requires that the Licensee require the use of appropriate personnel monitoring equipment by each individual who enters a restricted area (the HDR treatment room) under such circumstances that he receives, or is likely to receive, a dose in any

calendar quarter in excess of 25 percent of the occupational dose limits specified in 10 CFR 20.101(a). The treatment room constituted a restricted area because access to this area was controlled by the Licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. See 10 CFR 20.3(a)(14). With a 4.2 Curie iridium-192 source in the unshielded configuration, an individual entering the treatment room would be likely to receive a dose in excess of 25% of the occupational dose limits specified in 10 CFR 20.101(a).

Moreover, 10 CFR 20.202(a)(3) requires that the Licensee require the use of personnel monitoring equipment by each individual who enters a high radiation area. The treatment room constituted a high radiation area because, when the source is in an unshielded configuration, radiation levels in the treatment room are such that a major portion of the body could receive in any one hour a dose in excess of 100 millirem. See 10 CFR 20.202(b)(3). The Licensee was well aware of this fact, because it had posted the room as a high radiation area at the time of the November 16, 1992 event.

The requirement that the Licensee supply and require the use of appropriate personnel monitoring equipment does not depend on the individual's perception of a radiation hazard, but rather on the fact of a radiation hazard that may result in an exposure in excess of the limit in § 20.202(a)(1), or that requires posting as a high radiation area as per § 20.202(a)(3). Any time that the authorized user (AU) supervised the use of the HDR unit, he could be called upon to make an emergency entry into the treatment room with the source in an unshielded configuration. The Licensee should have been well aware of this fact, because the license application specifies training for its employees in emergency procedures involving entry into the treatment room with the source in an unshielded configuration. See License Condition 17, Application dated June 1, 1990, Item 10.15.C. Thus, the Licensee should have assured that the AU wore his personnel monitoring equipment whenever he supervised the use of the HDR unit. The AU did enter the treatment room with the source in an unshielded configuration and he was not wearing his personnel monitoring equipment. Therefore, the NRC concludes that Example III.C.1 occurred as stated in the Notice. Moreover, even if the Licensee had provided an adequate reason to withdraw Example III.C.1, Violation III.C still occurred as evidenced by the