NRC Evaluation of Licensee Response to Violation III.D.5

The issue of the Severity Level of the violation is addressed in the evaluation of the Licensee's response to Violations III.A and III.B above.

Summary of Licensee's Response to Violation III.D.6

The Licensee states that since it does not have sufficient knowledge as to the specific truth regarding whether ancillary personnel (specifically, housekeeping personnel) were informed about radiation hazards associated with a 3.7 curie iridium-192 source in a source container located in the High Dose Rate (HDR) afterloader treatment room, it must deny this violation. The Licensee believes that, in any event, Violation III.D.6 would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.D.6

Housekeeping personnel interviewed by the NRC staff were not aware of the radiation hazards associated with a 3.7 curie iridium-192 source. Specifically, on December 4, 1992, OSC housekeeping personnel unlocked the area where the iridium source was being stored following the source retrieval operation and accompanied NRC inspectors into the area, and the housekeeping personnel had not been informed about the radiation hazards associated with the source. Therefore, the NRC concludes that Violation III.D.6 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 Violations III.A and III.B, above.

Summary of Licensee's Responses to Violations III.E-F

The Licensee admits the violations but believes that Violation III.E would constitute a Severity Level V violation and that Violation III.F would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.E-F

The issue of the Severity Level of the violations is addressed in the evaluation of the Licensee's response to Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.G

The Licensee states that daily interlock checks were consistently done by individuals at IRCC, and that there was no requirement for the Licensee to review such completed checks as of December 1992. In addition, the Licensee notes that such checks would

have been reviewed at an annual audit. The Licensee believes that, in any event, Violation III.G would constitute a Severity Level IV violation.

NRC Evaluation of Licensee's Response to Violation III.G

Licensee technologists interviewed by the Incident Investigation Team (IIT) indicated that daily HDR interlock checks routinely were not performed as required. This is corroborated by the fact that there is not a log record for every check required. The Statements of Consideration for 10 CFR 35.25, 'Supervision'', state: "The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety [emphasis added]." See 51 Fed. Reg. 36940. While the Licensee was not required to review each and every check on a daily basis, it was required, pursuant to 10 CFR §§ 35.11, 35.25(a)(2), and 35.25(a)(3), to perform periodic reviews at a frequency sufficient to provide reasonable assurance that individuals working under the supervision of an authorized user were complying with, among other things, License Condition 17 with respect to the performance of daily interlock checks. It is clear from the fact that the noncompliance was occurring. undetected to the Licensee, that a single audit at the end of the year would not suffice. The NRC concludes that Violation III.G 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 Violations III.A and III.B, above.

Summary of Licensee's Response to Violation III.H

The Licensee denies the violation and states that at all times the RSO fully complied with relevant regulatory requirements, including implementing and distributing policies and procedures, and gathering materials. The Licensee also states that the RSO was immediately notified about the November 16, 1992 incident and instructed personnel how to respond appropriately.

NRC Evaluation of Licensee Response to Violation III.H

The Licensee provides no information to support its general assertion that it complied with all regulatory requirements or to refute the facts documented in the Incident Investigation Team (IIT) report, and the investigation by NRC's Office of

Investigations (OI), upon which the violations are based. Accordingly, the NRC concludes that the violation occurred as stated in the Notice.

Summary of Licensee's Response to Violation III.I

The Licensee admits that the RSO conducted the experiment, but states that the RSO took all measures to assure that such experiment was done safely and without risk, and this was not a willful violation but was done for the purpose, in part, of radiation safety. The Licensee believes that, in any event, Violation III.I would constitute a Severity Level IV violation.

NRC Evaluation of Licensee Response to Violation III.I

The Licensee admits that the RSO conducted the experiment and does not deny that the RSO changed the area of use of iridium-192 from the shielded therapy room to an area outside the building without first applying for or receiving a license amendment authorizing the change. The Licensee and its RSO may not pick and choose which regulatory requirements they will follow, even if they believe that noncompliance would somehow further radiation safety. 10 CFR 35.13(e) requires that the Licensee apply for and receive a license amendment before changing the area of use specified in the license. Moreover, willfulness is not a necessary element of a violation of 10 CFR 35.13(e). Accordingly, the NRC concludes that Violation III.I 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 Violations III.A and III.B, above.

Summary of Licensee's Response to Violations III/J.1–3

The Licensee states that its intent was not to become a shipper or a carrier of licensed material but under the extenuating circumstances, the Licensee contacted the NRC and was told what to do to retrieve the source. In addition, the Licensee states that at no time did the NRC attempt to alert the Licensee about the regulations cited in the Notice. The Licensee states that at the time of the incident, it did not transport sources, and as such was not generally knowledgeable about such. The Licensee further states that the Licensee took extreme precautions and brought the source back in a safe, secured container. Finally, the Licensee states that since it quickly retrieved the source after the NRC specifically told the Licensee to get the source, it would be unfair to cite the Licensee for these