

violations. The Licensee believes that, in any event, Violations III.J.1-3 would constitute Severity Level V violations.

NRC Evaluation of Licensee Response to Violations III.J.1-3

Prior to the incident, the Licensee requested a license amendment to permit it to transport licensed material as part of its licensed activities. License Condition No. 15 of Amendment No. 03, dated August 19, 1992, authorized the Licensee to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material". Therefore, the Licensee should have been familiar with the provisions of 10 CFR Part 71. In any case, the Licensee transported the radioactive source on December 1, 1992, and therefore was bound by the requirements in 10 CFR 71.5(a). The fact that the NRC advised the Licensee to retrieve the Licensee's source does not excuse the Licensee from the requirements of Part 71, nor does it excuse the Licensee from its ignorance of the requirements of Part 71. At no time did NRC suggest that applicable regulations should not be followed. Since these requirements were not met, the NRC concludes that Violations III.J.1-3 occurred as stated in the Notice. 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 Request for Mitigation

The Licensee states that subsequent to the Indiana event, Licensee management took corrective action by: immediately and voluntarily suspending HDR treatments at the Licensee's facilities that did not have full-time physicists for HDR treatments in order to review its entire HDR program; fully and timely complying with any and all Confirmatory Action Letters (CALs); replacing its RSO with a brachytherapy specialist; replacing multiple contract physicists; and hiring additional, qualified full-time physicists. The Licensee states that its proposed replacement of the RSO constitutes corrective action regarding all issues raised by the NRC, and notes that its new RSO has regularly been physically present at the Greater Pittsburgh and Greater Harrisburg facilities to review the entire HDR program.

The Licensee also notes that it has completely modified its HDR program, that the revised program has been approved by the NRC, and that Licensee management has been highly involved with the HDR program and has met on

a regular basis with the new RSO. In addition, the Licensee notes that it has restructured its physics program, which has resulted in at least quarterly training/refreshers courses in radiation safety and regulatory compliance at all facilities for all staff. Further, the Licensee notes that it is authorized users have attended an intensive training session with the new RSO regarding HDR usage, safety and emergency responses. The Licensee also notes that it hired a Certified Health Physicist (CHP) as Vice President of Regulatory Affairs and gave the CHP broad management authority, and that the CHP is responsible for the day-to-day radiation safety program company-wide.

The Licensee also states that it believes that the fines imposed are inappropriate and unsupported by the facts and applicable law. The Licensee states that to apply the \$100,000 per violation discretionary fine on the Licensee is now warranted and is unfair. In addition, the Licensee states that the NRC has attempted to impose the \$100,000 fine twice for one alleged failure, that being the alleged failure by the authorized user to do a survey with a hand held survey meter; and asserts that the loss of the source was not a separate action and cannot be separated from the alleged survey failure. With respect to the \$80,000 fine for the violations in Section III, the Licensee submits that the alleged violations, even if true, do not constitute a Severity Level II problem. The Licensee claims that it appears that NRC has not taken the past exemplary conduct of the Licensee into consideration and the Licensee requests that this conduct be reviewed again.

The Licensee cites a number of enforcement sanctions taken by the NRC against other licensees, which the Licensee believes supports its claim that the sanction imposed on the Licensee is not only unfair and inappropriate, but unlawful. The Licensee requests that the fines be reduced to \$14,000.

NRC Evaluation of Licensee's Request for Mitigation

Pursuant to Section 234 of the Atomic Energy Act, as amended, the NRC is authorized to impose civil penalties of up to \$100,000 per violation per day for each day that a violation continues. Normally, proposed civil penalties are determined after application to the base civil penalty of the mitigating and escalating factors in Section VI of the Enforcement Policy, including corrective action and licensee performance. Section VII.A of the Enforcement Policy provides, however, that notwithstanding the outcome of the

normal civil penalty adjustment process, the NRC may exercise its full enforcement authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violations at issue and conveys the appropriate message to the licensee, in order to provide an appropriate sanction when particularly serious violations or serious breakdowns in management controls have occurred. In view of the particularly serious violations, which resulted in the death of a patient and exposure of numerous members of the public to radiation in excess of regulatory limits, and in view of the necessity of emphasizing to the Licensee the importance of meticulous management oversight of the radiation safety program, a very significant civil penalty was warranted. The NRC appropriately exercised its statutory authority when it proposed a \$100,000 civil penalty each for the violations in Section I and II of the NOV, and an \$80,000 civil penalty for the violations in Section III. The NRC also expects that these penalties will give all other similar licensees, including the successor licensees to OSC, an incentive to closely scrutinize their operations to avoid similar violations.

The Licensee's assertion that Problems I and II constitute a single violation is mistaken. Problems I and II involve violations of separate and distinct NRC requirements, with separate and distinct facts and consequences. Problem I involves a failure to perform surveys and to use radiation safety devices in violation of 10 CFR 20.201(b) and License Condition 17, which led to a misadministration resulting in acute radiation exposure and subsequent death of the patient. Problem II involves a loss of control of a radioactive source and the creation of radiation levels in unrestricted areas in violation of 10 CFR 20.206 and 10 CFR 20.105, which led to exposures of numerous members of the public to radiation in excess of regulatory limits. Therefore, separate violations are clearly justified. *Atlantic Research Corporation, ALJ-78-2, 7 NRC 701 (1978).*

The issue of the severity level of the violations in Section III of the NOV was addressed under "NRC Evaluation of Licensee's Response to Violations III.A and III.B."

The NRC acknowledges that the Licensee has taken corrective actions and is aware of the Licensee's past performance. However, in this case, the NRC exercised discretion to escalate the civil penalties, which supersedes the normal application of the adjustment factors, as explained above. In addition,