

document was in a notebook containing other HDR records. According to the inspection report, the facility Medical Director/RSO had no knowledge of the document. In addition, the Medical Director/RSO stated at the time of the inspection that no one at the facility had received training on the document. Further, at the time of the inspection, the Licensee had not submitted its quality management program (QMP) to NRC as required by 10 CFR 35.32(f)(2). Since the Medical Director/RSO had no knowledge of the QMP, had not trained the staff on the QMP, and had not submitted the QMP to NRC, it is clear that the QMP was neither established nor maintained so as to provide high confidence that radiation from byproduct material would be administered as directed by the authorized user. Therefore, the NRC concludes that this example of the violation did occur.

Summary of Licensee Response to Example E of the Violation

The Licensee admits this example, but states its belief that this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example E of the Violation

The issue of severity level is addressed below under "NRC Evaluation of Licensee's Request for Mitigation."

Summary of Licensee Response to Example G of the Violation

The Licensee states in its response that it denies this violation. The Licensee states that it believes that certain records were maintained and that Omnitron also kept records for the benefit of the Licensee. The Licensee, in its letter dated December 1, 1994, provided copies of shipping papers showing the transfer of sources back to Omnitron, and copies of leak test results performed on sources by Omnitron. The Licensee believes that, in any event, this would constitute a Severity Level V violation.

NRC Evaluation of Licensee's Response to Example G of the Violation

The NRC staff has reviewed the records submitted by the Licensee on December 1, 1994. The particular shipping records that the Licensee submitted, which include the transferee, isotope, activity, and date, meet the requirement for records of the transfer of byproduct material. The leak test records that the Licensee submitted meet in part the requirement for records of receipt of licensed material. The leak test records did identify the transferor, isotope, and activity; but not the date of receipt. However, because the Licensee has other records, such as source exchange records, that identify the date of receipt, the NRC is withdrawing this example of the violation. The withdrawal of this example of the violation does not change the fact that the violation occurred, nor does it affect the appropriateness of the amount of the civil penalty assessed for the violation in this case, given the nature of the violation and the numerous other examples of the violation that are not being retracted.

Summary of Licensee's Request for Mitigation

The Licensee states in its response that it has taken numerous corrective actions to strengthen and improve all aspects of its radiation safety program. The licensee also states that over the past eighteen months, it has attempted to continually review and update its HDR program and staff, and emphasize the importance of radiation safety and applicable regulations. In addition, the Licensee indicates that management has attended courses regarding RSO duties and responsibilities. The Licensee also notes that five patients were treated with the HDR unit between March 1992 and December 1992 and there were no misadministrations or incidents.

The Licensee states that it: (1) Immediately and voluntarily suspended all HDR treatments in order to review the entire HDR program; (2) fully and timely complied with any and all CALs; and (3) replaced its contract physicist with a full-time physicist who, as RSO under the license, would provide necessary onsite RSO continuity needed to assure Licensee management and the NRC that the HDR program could run safely and in accordance with all regulations at all times. The Licensee also states its belief that the replacement of the RSO constitutes required and necessary corrective action regarding the identified issues, noting that the new physicist has held quarterly meetings where radiation safety, and regulatory issues have been reviewed with the staff. According to the Licensee, staff members have attended additional outside training and the authorized users have attended a six hour Radiation Safety Officers Review Course. In addition, the Licensee states that it has hired a Certified Health Physicist to assist in the coordination and oversight of all aspects of the Licensee's radiation safety program.

The Licensee states its belief that by hiring a full-time physicist to serve as RSO and obtaining the assistance of the Certified Health Physicist, it has clearly demonstrated that it has committed the resources necessary to develop and implement an appropriate, comprehensive and long lasting commitment to address the root cause of the violations. The Licensee believes that its new program, which permits only the physicist and physician to be involved with actual HDR patient treatments, will assure the NRC that none of the examples of the violation will be repeated.

The Licensee contends that a fine of \$80,000 for what the Licensee terms "a number of Level IV and V violations" is arbitrary, capricious and unsupported by any of the NRC rules, regulations and/or legislative history. In support of this argument, the Licensee claims that similar enforcement actions involving similar violations by Part 35 licensees resulted in substantially smaller penalties. The Licensee further states that these citations collectively do not constitute a Severity Level II program and, in any case, the maximum penalty should be \$8,000 before any mitigation. The Licensee asserts that it has an exemplary record having had no previous violations or misadministration. The Licensee cites a number of NRC Enforcement sanctions which

the Licensee believes supports its claim that the sanction imposed on the Licensee is inappropriate.

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 past 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. Given the seriousness of the violation in that the RSO failed to devote time or attention to the radiation safety program and that corporate management created the environment in which this was allowed to occur, a large civil penalty is warranted to emphasize the unacceptable performance of the Licensee, its RSO, and its corporate owner; and to emphasize the need for the Licensee and its corporate owner, as well as other licensees engaged in similar activities, to assure that controls are in place to avoid similar violations. The NRC appropriately exercised its statutory authority when it proposed an \$80,000 civil penalty for the violation.

As the Licensee's arguments that some of the examples are appropriately classified at Severity Level IV or V, the NRC did not categorize the individual examples of the violation in the Notice by severity level. Rather, the NRC categorized the single violation, including all of the listed examples, at Severity Level II. The violation is appropriately categorized at Severity Level II because it is of very significant regulatory concern and involved high potential impact on the public. Enforcement Policy Section IV. The guidance given by the examples in Supplements I-VII of the Enforcement Policy is neither exhaustive nor controlling in classifying the severity level of violations. The NRC reviews each enforcement action on its own merits to ensure that the severity level of a violation is characterized at the level best suited to the significance of the violation, which may warrant an adjustment to the severity level categorization. Enforcement Policy, Section IV. In this case, the violation represents a near total failure of the RSO to address her regulatory responsibilities and an equally serious failure of licensee management to exercise oversight over the radiation safety program in order to ensure that regulatory requirements were met, all of which created a high potential impact on the public for an incident similar to the November 1992 misadministration and