

Further, the licensee provided a list of 16 other Severity Level III enforcement actions that the licensee maintains are similar to its case.

NRC Evaluation of Licensee's Response Contesting Classification of the Three Violations at Severity Level II

In assessing the significance of violations, and assigning an appropriate Severity Level, the NRC considers the actual and potential consequences of the violations, their impact on the regulatory process, and any willful aspects of the violations, as noted in section IV.A of the NRC enforcement policy (NUREG-1600). The supplements to the enforcement policy provide examples of different Severity Levels and serve as guidance in determining the appropriate Severity Level for the violations, as noted in section IV.B of the enforcement policy. In this case, since the violations included the failure to have an AU and RSO, the violations would normally have been classified at Severity Level III in accordance with section C.8 of Supplement VI of the enforcement policy. However, section IV.A.4 of the enforcement policy specifies that violations may be considered more significant if they include indications of willfulness. In deciding whether to increase the significance of the violations, the NRC considers the positions and responsibilities of the persons involved, the significance of the underlying violations, the intent of the violators, and the economic advantage gained.

In this case, the NRC maintains that the violations were deliberate, notwithstanding the licensee's denial. As noted in the NRC October 22, 2002, letter transmitting the notice of violation and proposed imposition of civil penalty, the NRC considered the following facts in concluding that the violations were deliberate: (1) The VP prepared the NRC license application in October 2000, with the aid of a consulting physicist, and he listed an individual (a physician) as the AU and RSO on the application; however, the named individual was never employed by AMINS and never performed the duties of the AU or RSO at AMINS; (2) from June 2001 through November 2001, AMINS staff listed that individual as the AU of record when it ordered and administered radiopharmaceuticals on approximately 590 occasions; (3) in October 2001, a consulting physicist conducted an audit that revealed that the duties of the AU/RSO had not been performed, and he briefed the licensee regarding the problem at the end of the audit, yet NRC licensed activities continued until the NRC inspection on November 30, 2001; (4) the VP, when interviewed by an OI investigator, admitted that he knew the facility was required to have an AU and RSO and knew as early as June 2001 that not having an AU and RSO was a problem, but he did not take action to correct the situation; and (5) both the VP and COO admitted to the OI investigator that there were financial considerations associated with keeping the facility open.

Furthermore, the violations were the result of the actions by senior individuals in the organization (namely a Vice President and the Chief Operating Officer), and there was

an economic advantage to the licensee when it performed 590 administrations of radioactive materials at a time when it did not have an RSO and AU. Accordingly, even though there were no safety consequences identified from these violations, and actions were taken against both the Vice President and Chief Operating Officer, by both the licensee and the NRC, the NRC maintains that it was appropriate to increase the Severity Level classification from a Severity Level III to a Severity Level II in this case, and that such an increase is consistent with NRC policy and past determinations. In addition, contrary to the licensee's assertion, the 16 enforcement actions listed in the licensee's response are not similar to the circumstances of the AMINS enforcement action. Only six involved medical or human uses, and each of those six only involved one or two incidents of regulatory violations.

5. Summary of Licensee's Response Contesting the Amount of the Civil Penalty and Requesting Withdrawal or Reduction of the Civil Penalty

The licensee contests the amount of the civil penalty, contending that the NRC has abused its discretion by proposing a civil penalty of \$43,200. In support of that contention, the licensee reiterates that it denies two of the three violations that were classified as the Severity Level II problem. In addition, the licensee maintains that it should be given credit for notification, asserting that the COO and VP voluntarily informed the inspector of the violations. Also, the licensee stated that even if it is not entitled to credit for identification, the violations should be classified at Severity Level III and the penalty should not exceed the base amount of \$3000 for a Severity Level III. Finally, the licensee states that the use of weekly civil penalties was not warranted and was inconsistent with prior NRC cases, and cited examples of prior enforcement actions that the licensee believes to be inconsistent with the action taken against the licensee.

NRC Evaluation of Licensee's Response Contesting the Amount of the Civil Penalty and Requesting Withdrawal or Reduction of the Civil Penalty

The NRC disagrees that it has abused its discretion in determining the amount of the civil penalty in this case. For the reasons set forth in sections 3 and 4 above, the NRC maintains that all three violations occurred as stated in the notice, and were appropriately classified as a Severity Level II problem.

In addition, the NRC also maintains that the licensee is not entitled to credit for identification because the violations were identified by the NRC when the inspector arrived at the site on November 30, 2001. The NRC was not informed of such violations prior to that inspection, nor were there any indications in licensee's records identifying the violations. During that inspection, the NRC learned that the licensee's consulting physicist had identified the failure to have an AU during an audit, and briefed the licensee regarding the problem on October 3, 2001.

Finally, as noted in the October 22, 2002, letter transmitting the notice of violation and proposed imposition of civil penalty, the

NRC decided that consideration of daily civil penalties was appropriate in this case, due to the multiple instances of deliberately ordering and administering byproduct material to human patients without the benefit of a physician authorized user and a radiation safety officer, the level of management involved, the economic benefit associated with continuing to operate without an AU and RSO, and the failure to correct the problem even after the findings of the licensee's consultant on October 3, 2001. The NRC has also reviewed the enforcement cases referenced by the licensee, and finds that the circumstances in this case are not similar to any of the cases cited. Accordingly, the NRC maintains that it is appropriate to issue: (1) A base civil penalty amount of \$4,800 for the occurrence of the violations between March 2001 and October 3, 2001; and (2) additional civil penalty in the base amount of \$4,800 for each of the eight weeks that the violations continued even after the consultant identified the problem to the licensee on October 3, 2001. Therefore, the licensee has not provided an adequate basis to withdraw or reduce that civil penalty.

6. NRC Conclusion

The NRC has concluded that the Licensee did not provide an adequate basis for withdrawal of any of the violations, or for withdrawal or reduction of the civil penalty amount. Accordingly, the proposed civil penalty in the amount of \$43,200 should be imposed.

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NUCLEAR REGULATORY COMMISSION

Application for a License To Export a Utilization Facility

Pursuant to 10 CFR 110.70(b)(1) "Public notice of receipt of an application," please take notice that the Nuclear Regulatory Commission has received the following request for an export license. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link <<http://www.nrc.gov/NRC/ADAMS/index.html>> at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

In its review of the application for a license to export a utilization facility as