

set forth in the notice of violation that the Licensee admitted, this Order should be sustained.

Dated in Rockville, Maryland, this 19th day of February, 2003.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

*Deputy Executive Director for Materials,
Research and State Programs.*

Appendix

Evaluations and Conclusion

On October 22, 2002, a notice of violation and proposed imposition of civil penalty (notice) was issued for violations identified during an NRC inspection conducted at the Licensee's facility located in Easton, Pennsylvania. The penalty was issued for three violations that were classified as a Severity Level II problem. The Licensee responded to the notice in a letter, dated November 21, 2002. In its response, the Licensee: (1) Admits the first of the three violations that were classified as a Severity Level II problem; (2) denies the other two violations that were part of the Severity Level II problem; (3) contests the Severity Level II classification for the three violations; (4) contests the amount of the civil penalty for the Severity Level II problem; and, (5) admits two other violations that were classified at Severity Level IV. The NRC's evaluation and conclusion regarding the Licensee's request is as follows:

1. Restatement of the Three Violations Classified at Severity Level II and Assessed a Civil Penalty

A. 10 CFR 35.11 requires, in part, that a person shall not use byproduct material for medical use except in accordance with a specific license or under the supervision of an authorized user as provided in 10 CFR 35.25.

Contrary to the above, from June 2001 to November 30, 2001, a Nuclear Medicine Technologist (NMT) used byproduct material for patient diagnosis on approximately 590 occasions, and the use by the NMT was not in accordance with a specific license. In addition, the NMT was not under the supervision of an authorized user.

B. 10 CFR 35.21(a) requires that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in daily operation of the licensee's byproduct material program.

Contrary to the above, from about March 2001 to November 30, 2001, the licensee conducted licensed activities, including ordering and administering radiopharmaceuticals on approximately 590 occasions, and during that time, the licensee had not appointed a Radiation Safety Officer responsible for implementing the radiation safety program, to ensure that activities were being performed in accordance with approved procedures and regulatory requirements in daily operations of the licensee's program.

C. 10 CFR 30.9(a) requires, in part, that information required by license conditions to be maintained by the licensee, shall be complete and accurate in all material respects.

License condition 15.A of the NRC license for AMINS requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in various documents, including the license application dated October 20, 2000.

Item 10, Attachment 10.6 of the NRC license application for AMINS dated October 20, 2000, requires that written records will be made that identify the Authorized User when ordering radioactive materials.

Contrary to the above, on November 30, 2001, information required to be maintained by the licensee was not complete and accurate in all material respects. Specifically, all records of radioactive materials ordered between March 2001 and November 2001 indicated that the Authorized User who ordered the radiopharmaceuticals was Dr. Brij Mohan Gupta (Dr. Mohan). These records were not accurate in that Dr. Mohan was not employed by the licensee as an Authorized User, nor did he function in that capacity. This statement was material because an Authorized User was required by the license and by NRC regulations for supervision of the administration of radiopharmaceuticals to patients.

These violations represent a Severity Level II problem (Supplement IV). Civil Penalty—\$43,200

2. Summary of Licensee's Response Denying Violation 1.B

The licensee denies Violation 1.B, involving the licensee not appointing an RSO responsible for implementing the program when the radiopharmaceuticals were ordered and administered on the approximately 590 occasions. The licensee contends that with the assistance of its consultant, it was able to assure regulatory requirements were met during daily operations of the facility.

NRC Evaluation of Licensee's Response Denying Violation 1.B

Although the licensee denies this violation, the licensee, in its response, admits that it was unable to finalize arrangements with the individual who was listed on its license as the RSO. Therefore, since such arrangements were never finalized, and since the individual listed as the RSO never served as the licensee's RSO, the licensee did not appoint an RSO, consistent with requirements, responsible for implementing the radiation safety program. Rather, the licensee identified an individual as the RSO who was not employed by the licensee either directly, or as a contractor or consultant, and who did not implement the radiation safety program at any time, including between March 2001 and November 30, 2001, when the radiopharmaceuticals were ordered and administered on the approximately 590 occasions. Therefore, even though the licensee indicates that it was able to assure, as evidenced by a subsequent review by its consultant, that other regulatory requirements had been met during daily operations of the facility, the licensee did not

provide an adequate basis for the NRC to withdraw Violation 1.B in the notice. Accordingly, the violation remains as stated in the notice.

3. Summary of Licensee's Response Denying Violation 1.C

The licensee denies Violation 1.C involving the creation of inaccurate records of the radioactive materials ordered on the 590 occasions. The records were considered inaccurate in that the licensee listed as the authorized user an individual physician who was not employed by the licensee and was not performing the duties of the authorized user. The licensee denies this violation because the physician was identified on the license as the AU, and the records were completed in a manner consistent with the license. The licensee states that it was not aware of any regulatory requirement that the authorized user be employed by the licensee.

NRC Evaluation of Licensee's Response Denying Violation 1.C

The NRC had determined that Violation 1.C occurred because information required to be maintained by the licensee was not complete and accurate in all material respects. Specifically, all records of radioactive materials ordered between March 2001 and November 2001 indicated that the Authorized User who ordered the radiopharmaceuticals was Dr. Brij Mohan Gupta (Dr. Mohan). These records were not accurate in that Dr. Mohan was not employed by the licensee, nor acting in any capacity, as an Authorized User.

In denying this violation, the licensee states that the crux of this regulatory requirement is that the licensee's records be accurate, and that the performance by the AU of his/her obligations is not the focus of this regulation but is covered under other regulations. The NRC maintains that these records were not accurate because the individual listed in the records as the AU was never employed by the licensee, nor did that individual otherwise serve or act as the AU (such as via a contractor or consultant arrangement). Therefore, the licensee did not provide an adequate basis for the NRC to withdraw Violation 1.C in the notice. Accordingly, the violation remains as stated in the notice.

4. Summary of Licensee's Response Contesting Classification of the Three Violations at Severity Level II

The licensee contests the Severity Level II problem classification for the three violations set forth in section I of the notice. The licensee contends that the violations were not willful; the VP and COO have been penalized; even if the VP and COO's actions were willful, the action taken against them obviates the need for substantial penalties to the licensee; there were no actual or realistic potential safety consequences as a result of the violations; and classification of the violations at a Level II is inconsistent with NRC policy and prior determinations. With respect to the last point, the licensee indicates that the seven examples of Severity Level II described in the HP supplement of the enforcement policy, relate to overexposures or unauthorized releases.