NUCLEAR PHARMACY OF IDAHO, Inc.

6225 Overland Rd. • Suite B • P.O. Box 6680 • Boise, Idaho 83709 • Tel: (208) 375-1255 • FAX: (208) 375-1441

October 23, 1994

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission.
Attn: Document Control Desk
Washington, D.C. 20555

Subject: Answer to a Notice of Alleged Violation Docket 030-32223

The notice of violation had errors of omission concerning our radioiodine effluent releases. We have provided the data to fully evaluate the release data.

NPI requests complete remission of the civil penalty since radioiodine effluent releases do not exceed levels which trigger a severity level III violation in accordance with the "General Sttement of Policy and Procedure for NRC Enforcement Actions" 10 CFR Part 2 Appendix C Supplement IV. NPI applied corrective action before the NRC identified this violation in its May 16-17, 1994 inspection. NPI took no corrective action after December 31, 1993 because we were in compliance on January 1, 1994 with the new regulations. This does not imply that we were not cognizant of the regulations. The new part 20 limits for radioiodine releases were taken into account and NPI elected to delay purchasing a charcoal filtered glove box until we could design and move into a new facility. We felt, and still do, that this was a prudent approach to a long term solution.

The factors used to adjust civil penalties addressed in Section VI.B.2 of 10 CFR Part 2 , Appendix C have been reviewed. The NRC escalated the base civil penalty 100% of the base value under section d, Prior Opportunity to Identify. This section states that escalation of the civil penalty based soley on

IE1A
1/1

prior notification is normally not warranted where the licensee appropriately reviewed the notification for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time. NPI has shown that corrective actions were planned, and were in fact being implemented between the first and second inspections. NPI took reasonable actions within a reasonable time.

NPI was given 50% base civil penalty reduction based on licensee past performance. These were the only areas the civil penalty was adjusted.

A civil penalty is imposed for a violation and is designed to emphasize the need for lasting remedial action and to deter future violations. Since NPI had immediately begun corrective action before the alleged violation was escalated to a severity level III, the civil penalty was unnecessary. NPI had already begun implementing their corrective actions before the violation was identified. The base civil penalties in table 1A or 1B do not reflect NPI's ability to pay. NPI is a small business. Because it is not NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business we ask for an "exercise of Discretion" in the form of a remission of the amount of the civil penalty. Up until now, NPI could afford NRC fees. For the first two years, our inspection fees were $1700 and our annual fees were $1800. Currently, our inspection fees have increased to $3300. We are still seeking remission or mitigation for the second inspection fee of $3300. Once these factors are taken into account, I feel very confident that the NRC can understand our position as a small business.

Sincerely,

Ned Gregorio

Ned Gregorio, Pharmacist

depends on going into the manufacturer's application programs. In other cases, one needs programs that read floppy disc or tape output from proprietary computers. Occasionally, one can find a manufacturer that is willing to modify its application program, but too often at the next software release, the modification no longer works.

To partially remedy this situation, a department purchasing a new acquisition computer should insist not only that the application programs be suitably modified, but that all new software releases must maintain those modifcations. Second, regions of the source code dealing with the database and header information should be made available to the purchaser; or, alternatively, one should obtain a guarantee that timely, designed software changes will be made before and after equipment purchase. Third, the purchaser should retain the right to install networking software and hardware without voiding service contracts.

Conclusion

From our seven years' experience with a completely filmless, all-digital imaging department, we have gained insights that should be useful to others contemplating an all-digital radiology department. Our nuclear medicine PACS system provides network transfer of studies from our seven-image acquisition computers to three multiple-study display 1024 x 1280 pixel workstations. The workstations have windows into our HIS, RIS, and reporting system, allowing each workstation to be a single terminal workstation for all radiologist functions. Network modems permit remote access to the 28GB database. Issues of backup, conference presentation, networking, PACS advantages, and salient principles may help guide the development of PACS by others.

Gerald M. Kolodny, MD
J.A. Parker, MD, PhD
Kevin J. Donohoe, MD
Dace Jansons, MS, CNMT, RT
Larry Barbaras
Douglas Wagenar, PhD
Beth Israel Hospital, Division of Nuclear Medicine

Dr. Kolodny is a staff member of the Harvard Medical School Joint Program in Nuclear Medicine; director of nuclear medicine, Department of Radiology, Beth Israel Hospital; an associate professor of radiology, Harvard Medical School. He was an inventor of the RTAS digital radiology reporting system, and holds stock in Sudbury Systems, the manufacturer of RTAS. Sudbury also provided the software development for the PACS described in this article.

News Briefs

Decreasing the NRC Fee Burden

The struggle with onerous NRC fees recently found hope on two fronts. Although the agency is charged by law to recover all of its expenses from its users and licensees, sometimes the distribution of fees seems to fall on certain parts of this population to the point of harm.

First, this Spring, efforts to overturn a heavy fee from nonprofit educational institutions succeeded. In early 1993, upon an order by the U.S. Court of Appeals of D.C., the NRC had deleted a provision that exempted nonprofit educational institutions from annual fees (see *Newsline*, October 1993, p. 30N). Striking the exemption would have meant an extra $62,100 annually for 38 research reactors at 33 universities, many of which are strapped for funds. Closing reactors could have affected nuclear medicine research and training. After the NRC published the new fee schedules, several potentially affected institutions filed a petition protesting such a pending loss to the public good. After a few months' consideration of this petition and comments on the proposed fee, the NRC reinstated the exemption.

Also, late this Spring, the U.S. Senate and House addressed the problem of NRC's user fees, which directly affect nuclear medicine by creating a large expense for the agency's medical licensees. Since 1990, as the NRC budget has increased and the agency passed costs on to licensees, these fees have increased over 1,400 percent, adding burden to practitioners and patients. The nuclear medicine lobby brought the problem to Congress' attention this year, and both chambers in turn addressed it in their reports to the commission. The Senate report notes that "This escalation of fees has caused 2,700 licensees (including 500 medical licensees) to drop their licenses since 1991, directly affecting the health and well-being of those dependent on the medical services," and recommended that, to reduce costs, the NRC should turn over much of the regulation of materials licensees to the States.

"The accepted fact in Washington is that the best way to get an agency's attention is to have the committees that appropriate the money give them direction," said J. Michael Hall, director of legislative affairs, Joint Government Relations Office. If so, the commission has received the message from its highest authority that steep fees only hurt nuclear medicine and national health. ■

Nuclear Medicine World Congress Gears Up

The Sixth Congress of the World Federation of Nuclear Medicine and Biology, to be held in the Sydney Convention and Exhibition Center in Sydney, Australia, October 23-28, has received a tremendous response in its call for abstracts. Over 1,100 abstracts were submitted, 372 were selected for oral presentation in 64 sessions, and 590 will be displayed as posters. There will be 15 "State of the Art" review sessions, each with three speakers of international renown covering the status of major nuclear medicine topics; more controversial topics will be covered in the Symposia series. There have been 95 entries for the Iio Award, out of which five finalists will be narrowed to the single awardee, who will be introduced at the Closing Ceremony by SNM Past President Henry N. Wagner, Jr., MD. SNM President James J. Conway, MD, will conduct the "International Pediatric Challenge." Parties interested in attending the Congress should contact the Sixth World Congress of Nuclear Medicine and Biol-