NRC Fines West Virginia Hospital

The Nuclear Regulatory Commission (NRC) has assessed Beckley Appalachian Regional Hospital in Beckley, West Virginia, $1,000 in civil penalties for several instances of non-compliance with NRC requirements. The NRC reports that the hospital has paid the penalty, which was reduced from $3,500 after the hospital pleaded inability to pay and noted that it had spent $5,991 on corrective actions.

Citing a corporate policy against releasing such information, Roger J. Wolz, administrator of the hospital, declined to discuss the NRC's action.

This assessment marks the second time in less than a year that the NRC has taken strong action against nuclear medicine units for non-compliance. In July the NRC published a notice in the *Federal Register* concerning Milford Hospital in Milford, Delaware, which was accused of failing to hold radiation safety committee meetings, failing to report misadministrations and falsifying documents (see *Newsline*, Nov. 1987, pp. 1653-1655, and Jan. 1988, p. 145.) These incidents suggest that the NRC may be demanding more from medical licensees than it has in the past.

'Raise the Sensitivity'

"I have the impression that we're focusing more on the medical area," said James Lieberman, director of the office of enforcement for the NRC. "We try to raise the sensitivity of the licensees. Ideally, when they hear of a problem, they'll look at their own facilities a little harder and take corrective action."

"They've been this way for a number of years," adds Barbara Y. Croft, PhD, associate professor of radiology at the University of Virginia in Charlottesville and president-elect of the Society of Nuclear Medicine. "I have the feeling that they make examples of people, but any regulatory agency does that."

The infractions cited by the NRC in this case—failure to perform wipe tests and failure to hold radiation safety meetings, among others— may appear minor to some, but not to the NRC. "I don't believe any one violation was extremely significant [at Beckley]," Mr. Lieberman said, "but if you're missing the little things, maybe you're missing the big things." He said that while the agency tries not to overreact, and realizes that human error will occur, it depends on hospitals to protect the public. "When you're working with nuclear matters, you've got to dot the i's and cross the t's," he said. "If it is a required test, there's a reason for it."

Container Leaks

Dr. Croft, who teaches radiopharmacy, tells her students that they must understand NRC requirements and that following them is important. Wipe tests may be the first indication of a leaking receptacle, for example, and she recalled incidents from some years ago in which contamination with iodine-131 and molybdenum occurred because of container leaks. Those responsible for radiation safety "are supposed to be doing their jobs," she said. "And that matters."

In its notice in the *Federal Register* dated March 25, 1988, NRC officials described their reasons for leveling civil penalties, the NRC term for fines, against Beckley. The notice said that during a routine unannounced inspection of the hospital's activities in July, 1987, the inspector found that the hospital had not conducted meetings of the Radiation Safety Committee at least once each calendar quarter as required. The hospital admitted the violation, according to the NRC, but said that it was misinformed by a vendor of nuclear imaging equipment. The notice added that this is similar to a violation cited in an NRC warning in December, 1986.

Radiation Survey Records

The NRC also said the hospital's radiation safety officer failed to review radiation survey records over an 11-month period in 1986 and 1987, when quarterly reviews are required. The hospital initially denied the violation, according to the NRC, saying that monthly reviews of the surveys had been conducted and that the NRC inspector had failed to check relevant documents. The NRC countered that the hospital had misunderstood which records the violation charge concerned. Once the matter was clarified, the hospital instituted corrective action, the NRC said.

In addition, the hospital was found not to have barium-133 on hand to calibrate a dose calibrator, which, according to NRC regulations in effect at the hospital, must be tested with cobalt-57, cesium-137 and barium-133 sources. The hospital admitted the violation, the NRC said, but explained that an NRC inspector had instructed the department to use cobalt-57, cesium-137 and cobalt-60 sources for performing calibration. The inspector denied giving specific instructions, and the NRC pointed out that in any case it is the licensee's responsibility to understand and comply with regulations. The NRC also concluded that this violation was similar to another violation recorded in December, 1986.

The NRC also faulted the hospital for failure to perform a wipe of the external surface of the final source container when opening packages of radioactive material. The hospital ad-

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mitted the violation, the NRC said, but cited extenuating circumstances, including following previous inspectors' instructions and a section in NRC regulations that says that wipe tests are not required of the final source containers unless there is reason to suspect contamination. The NRC rejected both contentions, noting that the NRC regulations the hospital cited were not operative at the time of the unannounced inspection in July. The device used for wipe tests was also found by the NRC to have a minimum detectable activity of about 22,000 dpm, while regulations require that the method for performing wipe tests be sufficiently sensitive to detect 200 dpm per 100 cm^2. The hospital responded that it was misinformed by the vendor and a previous NRC inspector and that appropriate equipment was obtained after the unannounced inspection.

The NRC added that the hospital obtained results of area wide surveys in units of millicuries but erroneously recorded them in units of millirem per hour. The hospital admitted the violation, but said it was misinformed by the vendor and that a previous inspector had reviewed the technique and approved of it. In response, the NRC noted that the licensee must not depend on an outside consultant or inspector, but instead must possess basic knowledge of routine instrument use. If a procedure is not specifically cited by an inspector, that does not mean the NRC automatically approves of what is being done.

Noting that the hospital is in the "economically devastated" Appalachian region, providing $508,145 in charity care for fiscal year 1986–87 and having an operating deficit for fiscal 1986–87 of $291,453, the NRC agreed to reduce its civil penalties to $1,000 from $3,500. A previous penalty of $5,000 had been reduced to $3,500 because the agency accepted the hospital's explanations for some apparent violations. The hospital was absolved of any violation associated with a film badge that recorded a high radiation exposure while out of its holder; the reading was determined to be in error. The NRC also withdrew a violation concerning how radiation exposure history was recorded in one case. ■

NRC to Revise Previous Proposal for Quality Assurance

The Nuclear Regulatory Commission (NRC) may adopt less-specific quality assurance guidelines than originally expected after meeting April 7 with representatives of the Society of Nuclear Medicine, the American College of Nuclear Physicians, the American College of Radiology, the American Association of Physicists in Medicine, and other interested parties, according to staff members with the NRC.

These less-specific guidelines, known as performance-based standards, would be in lieu of the prescriptive regulations originally published by the agency in October and discussed at NRC meetings since then (see *Newsline*, March 1988, pp. 283–286 and May 1988, p. 592). Performance-based standards provide goals without specifying how they are to be met, while prescriptive regulations delineate the specific procedures that must be followed for compliance.

The NRC has proposed additional quality assurance guidelines because of concerns about the misadministration of radiopharmaceuticals. According to agency data, 52 therapy misadministrations and 23 diagnostic misadministrations occurred from late 1980 through 1987. These errors included administrations of the wrong pharmaceutical, the wrong dosage, and administration to the wrong patient, and have been attributed to inattention to detail, lack of redundancy, and inadequate training and communication.

As a result of this change in direction, new guidelines for quality assurance are being developed by NRC staff. These will be submitted to the Commissioners for consideration and published in the *Federal Register* for public comment. The original April 29 deadline for NRC action was set aside, with no new deadline for a final rule yet established.

The Commission is also considering running a pilot study of the new proposal. A small number of licensees, probably representing a cross-section of facilities using nuclear medicine, would implement the new guidelines and report back to the Commission on their effectiveness. This idea may be in response to the comments of Carol Marcus, PhD, MD, head of the Nuclear Medicine Outpatient Clinic at the Los Angeles County–Harbor/UCLA Medical Center, who implemented the proposed rules as an experiment and uncovered problems.

While the Society and College originally opposed any additional NRC oversight of nuclear medicine procedures, the groups softened their stance once it became clear that the NRC intends to take some action to reduce misadministrations. Dr. Marcus testified at the most recent meeting that the October guidelines for prescribing the administration of iodine-123 and iodine-131 have worked well at her facility. ■