(continued from page 1007)
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. ■