News Briefs

NRC Commissioners Meet On Proposed Rule For Quality Assurance

The Nuclear Regulatory Commission (NRC) held a staff briefing in March on the status of the proposed rule to establish additional quality assurance criteria for the medical use of by-product material. This proposal was published in the *Federal Register* in October, and the NRC's Advisory Committee on the Medical Uses of Isotopes met in January to discuss it (see *Newsline*, March 1988, pp. 283-286).

The NRC staff presented its findings, which were that the error rate for misadministrations of radiopharmaceuticals is low; that misadministrations are potentially injurious to patients; that they potentially involve multiple patients; and that a "substantial fraction" were "abnormal occurrences," or errors serious enough that they must be reported to Congress. Misadministrations were attributed to lack of redundancy and inadequate communication among health care providers.

The staff also reported the Advisory Committee findings, which were that the proposed rule is unlikely to significantly change the misadministration rate; that the rule could cause a reduction in the quality of patient care because of diverted resources and treatment delays; that the rule is costly; and that there is a shortage of sufficiently trained personnel to implement the program. The Advisory Committee concluded that "there are less prescriptive ways, which would ultimately better serve patient care, for NRC to enhance and enforce quality assurance than the proposed rule," according to NRC staff.

Of the 69 letters of comment received by the NRC, 25% supported the proposal, staff members said. Supporters included the Commission on Radiation Therapy of the American College of Radiology and the College of American Pathologists. Among the 20% opposed were the American College of Radiology and the Society of Nuclear Medicine, and 55%, including the American Association of Physicists in Medicine, the American College of Medical Physics, and the National Council on Radiation Protection and Measurements, suggested changes. Those who opposed the rule cited the low probability of misadministrations, its cost and the inability of additional regulation to prevent human error.

The staff recommended that the five commissioners meet with Advisory Committee representatives prior to deciding on a final rule, which the NRC said would be ready for endorsement by the end of April.

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FDA Set to Reclassify NMR Instruments To Class II From Class III

The United States Food and Drug Administration (FDA) has published an announcement in the *Federal Register* seeking public comment on the agency's proposed reclassification of nuclear magnetic resonance (NMR) devices from Class III to Class II. This reclassification proposal is in response to the petitions of 13 NMR manufacturers and is consistent with the recommendations of the FDA's Radiologic Devices Panel.

When the Medical Device Amendment Act of 1976 was made law, all existing devices were classified as Class I (general controls), Class II (general controls and performance standards) or Class III (requiring premarket approval). New devices are automatically placed in Class III, which requires data collection to prove they are safe and effective, a process usually taking at least three years.

According to the *Federal Register*, the FDA panel recommended the reclassification to Class II because "there is sufficient publicly available information to demonstrate that the risks to health have been determined for the magnetic resonance diagnostic devices for which reclassification has been requested. The relationships between the device's safety and performance parameters and risks have been established by valid scientific evidence, and there is sufficient publicly available information to establish a performance standard to control the device's safety and effectiveness."

The panel also recommended that the FDA assign a low priority to establishing a performance standard for NMR, because "the quality of the data in the petitions was sufficiently strong in describing safety and effectiveness . . . so that assigning a low priority for standards development is appropriate. All currently marketed magnetic resonance devices have undergone premarket approval and, as a result, there is reasonable assurance of the device's safety and effectiveness."

The deadline for public comment is May 9, 1988.

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