NRC Proposes New Rules for Quality Assurance, Training and Experience

NRC Removes Nuclear Physicians from Hospital Licenses for Falsifying Records

During the past few months, the United States (US) Nuclear Regulatory Commission (NRC) removed two physicians from hospital licenses authorizing the use of radioactive byproduct materials. These actions were taken in response to NRC inspectors' discovering false statements on dose calibration records, fake documentation of radiation safety committee meetings, failure to report misadministrations, and attempts to cover up those misadministrations.

On July 2, 1987, the NRC published a notice in the *Federal Register* (pp. 25096–25097) for Milford Hospital in Milford, Delaware, demanding removal of the radiation safety officer from its license. On December 17, 1986, an NRC inspector found that daily constancy checks on a dose calibrator remained close to the same value for a six-month period, even though the check source had a relatively short half-life. The two technologists responsible for performing the daily checks at first said that they were done every day, but later admitted that the values were recorded without the checks being performed. If the radiation safety officer had adequately audited the records, according to the NRC, he would have noticed the constancy readings and should have questioned them.

In addition, the assistant administrator of Milford Memorial Hospital became concerned when he saw the minutes of one radiation safety committee meeting to which he had not been invited. When the radiation safety officer was questioned, he said that these meetings, required by the NRC license to be held quarterly, had not been held for the past year, and false records were created in an attempt to show that the meetings had taken place. The radiation safety officer later admitted to two NRC inspectors that the radiation safety committee had not held a meeting for more than 15 years.

Citing questionable integrity and competence, the NRC ordered that the physician be removed from the post of radiation safety officer, and suspended his authorization to independently use or supervise the use of licensed byproduct materials. In addition, the radiation safety program at Milford Memorial Hospital is now undergoing monthly audits by outside experts.

Misadministration Cover-Up

On August 28, 1987, the *Federal Register* (pp. 32623–32625) published an order to show cause why the medical use license at the Hines Veterans Administration (VA) Medical Center in Hines, Illinois, should not be modified to remove the assistant chief of the Nuclear Medicine Service, barring him from performing or supervising NRC-licensed nuclear medicine activities.

On August 14, 1986, an anonymous phone caller tipped off the NRC to three allegedly unreported misadministrations at the Hines Medical Center during the previous week. The acting chief technologist notified the assistant chief of the department shortly after at least two of the misadministrations, but the physician did not take any action to ensure that these events were reported to the NRC. The VA conducted an investigation, but the results were inconclusive because a nuclear medicine technologist lied for fear of contradicting the physician, according to results of a subsequent NRC inspection.

The first misadministration involved a patient scheduled for a bone scan who was mistakenly injected with a brain agent, followed by the bone agent. The physician later said that he had ordered the brain agent injected, but the technologist later stated to the NRC that no discussion of a brain scan ever occurred.

On the same day, a patient received a gallium-67 dose intended for another patient. When the acting chief technologist informed the same physician of this misadministration, the physician obtained a written prescription to perform a gallium scan on that patient from the acting attending physician, who had not been informed that the injection had already been administered.

Since the NRC does not regulate accelerator-produced radionuclides, the hospital was not required to report the gallium-67 misadministration. The physician's attempt to conceal it, however, "shed doubt" on his "credibility and ability to ensure the safe conduct of licensed activities," according to the NRC.

Two days later, a patient at the Hines VA Medical Center, who was scheduled for a gallium-67 study, received a bone scan intended for another patient. This misadministration was not reported to the NRC as required.

"These actions demonstrate the

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NRC's renewed and heightened interest in material false statements and lack of candor," said Norman L. McElroy, leader of the NRC Medical and Academic Section. He clarified that a misadministration does not constitute an infraction of NRC rules, which simply require the reporting of such an event. The NRC realizes that a certain amount of human error is very difficult to prevent, but the agency "will not tolerate lying," said Mr. McElroy.

Violations Are Not Typical

[The examples cited above do not reflect typical patterns within the nuclear medicine community. A comprehensive NRC study found that the annual rate of diagnostic misadministrations in the US is 1×10^{-4}, calculated from an estimated 1,500 misadministrations compared with the estimated 20 million diagnostic nuclear medicine procedures *in vivo* performed annually (see *Newsline*, July 1986, pp. 1102–1107). With respect to radiation safety regulations, the NRC has said that "the medical community generally shows a high rate of voluntary compliance."]

When the NRC revised its "Medical Use of Byproduct Material" regulations [Title 10 Code of Federal Regulations (CFR) Part 35] in 1986, the staff recommended to the commissioners that the misadministration reporting requirement for diagnostic radiopharmaceuticals be dropped because the hazard was not sufficient to warrant additional safety requirements (see *Newsline*, Feb. 1987, pp. 151–153).

The commissioners, however, decided that the requirement should be retained, and that it should be made an item of compatibility for NRC agreement states. [There are 29 agreement states, which formulate their own radiation safety regulations that must include certain items from NRC regulations as a matter of compatibility; there are 21 nonagreement states, in which byproduct material safety is regulated by the NRC.]

In December 1985, the NRC Office for Analysis and Evaluation of Operational data prepared a case study of 27 misadministrations in teletherapy (16), brachytherapy (5), and radionuclide therapy (6) that occurred from November 1980 through July 1984. The majority of these misadministrations were caused by failure to assay or calibrate the dose, administering the wrong radiopharmaceutical, brachytherapy sources placed incorrectly in applicators, illegible prescriptions, and arithmetic errors.

When a hospital treated the wrong patient with 150 rads early last year, one NRC commissioner was reportedly incredulous that a medical licensee could expose a member of the public to a radiation dose of that level without getting a citation. If a nuclear power plant accidentally exposed someone to 150 rads, the NRC would definitely take action.

On October 2, 1987, the NRC published a proposed rule in the *Federal Register* (pp. 36942–36949) for basic quality assurance requirements in the therapeutic use of byproduct material, and in any application—therapeutic or diagnostic—of any radioiodinated agent.

Concerns Raised About Radioiodine Thyroid Studies

"Radioiodine studies were included in this rule because we've had several instances where patients scheduled for iodine-123 studies received iodine-131 by mistake," Mr. McElroy explained during a government relations seminar held last September at the Interim Meeting of the American College of Nuclear Physicians (ACNP). "We've also seen cases where a patient who should have received 10 μCi of iodine-131, for example, actually received 5 mCi—cases where a patient walked into the nuclear medicine department with a relatively healthy thyroid and walked out with a thyroid dose of 8,000–15,000 rads," he added.

The deadline for public comments is December 1, 1987.

An advance notice of proposed rulemaking, published in the same issue of the *Federal Register* (pp. 36949–36953), indicates that the NRC is ready to enact comprehensive quality assurance requirements for the medical use of byproduct materials. "We raise several issues in this notice, such as what quality assurance programs exist now, how much they cost, what can be done to reduce the chance of a misadministration and improve the likelihood of protecting public health and safety," said Mr. McElroy.

The deadline for public comments is December 31, 1987.

One attendee at the government relations seminar warned members of the nuclear medicine community to carefully read between the lines—even the sections of the proposed rules that deal with radiation therapy. "The NRC is going to do the same thing to nuclear medicine that it did to the nuclear power industry," one observer predicted.

Technologist Training and Experience Requirements

The saga of training and experience requirements for NRC licensure to use byproduct radionuclides in medicine will soon add new characters—allied health professionals—to the cast of nuclear medicine physicians, cardiologists, and radiologists. In January 1984, the American College of Cardiology asked the NRC to reduce training and experience requirements for cardiologists to four months. The issue grew into a heated controversy, and several medical organizations and individuals submitted widely diverse opinions in 1985 to the NRC (see *Newsline:* March 1985, pp. 220–223; June 1985, pp. 557–558; May 1986, p. 590).

Training and experience requirements are covered in 10 CFR Part 35, but when the NRC published its revised version of those regulations, the agency announced that it would review training and experience requirements in a separate project. Earlier this year, the NRC staff drafted a proposal that essentially would have reduced the requirements for all physicians licensed to use radionuclides in diagnostic studies, with special considerations for physicians who limit their practices to one organ system. The NRC commissioners, however, objected to reducing training and experience requirements (particularly in light of the problem of therapeutic misadministrations), and directed the staff to reexamine the whole issue.

The *Federal Register* will soon publish a notice that discusses NRC training and experience requirements for: physicians providing a wide range of diagnostic procedures; physicians providing single-organ studies; nuclear medicine technologists; and radiation therapy physicians, physicists, dosimetrists, and technologists.

Questions Raised About Regulating Assistants

"We also raise the question of how to regulate technicians who have been trained in a hospital setting to perform a few radiation safety procedures and a few simple nuclear medicine clinical procedures, or who assist in the application of radiation therapy but who do not actually administer it," said Mr. McElroy. "We're also asking for public comment on whether the NRC should get involved in certain areas and, if so, how involved."

The public will have 60 days to comment.

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Linda E. Ketchum

California Researchers Escape Criminal Charges for Radiation Safety Violations

In what seemed like a surprise attack to officials at the University of Southern California (USC), a Los Angeles city attorney called a press conference last March to announce that he had filed criminal complaints against USC and 10 of its researchers for 179 violations of state radiation safety regulations. The University was officially notified of the charges several hours after the press conference.

The researchers—who were never arraigned—are professors of microbiology, obstetrics and gynecology, biochemistry, and radiopharmacy. Charges included: failure of the radiation safety committee to meet quarterly and to audit the radiation safety program annually; failure to perform thyroid assays for iodine-125; unlawful transfer of radioactive material; inadequate employee training; failure to calibrate survey meters, to perform leak tests on sealed sources, and to monitor trash bins daily; evidence of eating, drinking, and smoking near unsealed radioactive sources; and many other counts involving record-keeping.

The charges stemmed from inspections by the Radiologic Health Branch of the California Department of Health Services (DHS), after which the DHS sent a 21-page letter to USC on January 28, 1987, listing 77 violations against USC and 17 scientists and physicians. [California is an "agreement state," which means that it makes and enforces its own radiation safety regulations under an agreement with the United States (US) Nuclear Regulatory Commission (NRC).] The university sent the DHS a written response to each violation on February 12, 1987.

With respect to nuclear medicine, the DHS initially cited as one violation the "failure to provide discharge instructions (outlining precautions to be taken at home) to patients receiving therapeutic quantities of iodine-131." A memorandum from the Nuclear Medicine Section of the USC School of Medicine, however, explained to the DHS that these patients are not discharged until the exposure rate measured at one meter away is 2 mrem/hour or less, and that the National Council on Radiation Protection and Measurements (NCRP) states that no precautions to protect family members from exposure need to be taken at that level. This violation was not included in the criminal charges.

A joint criminal investigation conducted in March 1987 by the DHS and the Los Angeles city attorney's office found "a pattern of incredibly cavalier conduct" in USC's radiation safety program, according to the city attorney. On October 1, all charges were dismissed except 15, to which USC pleaded no contest. USC will be on probation for 18 months, pay a $25,000 fine, and establish a three-year fellowship in radiation safety.

One observer noted that behind-the-scenes politics may explain some of the high-profile actions taken to resolve problems with USC's radiation safety program, and why these problems exist. The NRC, for example, has put pressure on the California DHS to strengthen its radiation safety enforcement program. Personality differences among members of the radiation safety committee and USC administrators over the past few years have destabilized the radiation safety program. In addition, this source believes that the Los Angeles city attorney plans to run for higher office, and wants to establish a reputation as a "prosecutor of polluters."