News Briefs

NRC Sending Teams to Study Risk in Medical Misadministrations

The U.S. Nuclear Regulatory Commission (NRC) embarked this year on a twelve-month program in which medical experts and risk analysts will be dispatched to medical therapy radioisotope misadministrations within 48 hours of their occurance to study the "risk implications" of such accidents. The risk analysis project is, according to NRC officials, a trial attempt to identify sources of error that might be eliminated by new or revised regulations, as well as a means to define the effectiveness of existing rules. Investigators will compare the corrective actions of medical facilities to requirements cited in the NRC's 10 CFR Part 35 regulations and the recently adopted Quality Management Rule.

"By looking at the events, we are trying to see if we can more effectively regulate," says NRC senior risk analyst and project manager Patricia Rathbun, PhD. "We're asking, 'Were the regulation in place differently, could it have prevented the incident?'"

The Idaho National Engineering Laboratory (INEL) finalized a $600,000 contract for the project with the NRC in May 1991. The funds will allow INEL to send investigative teams of medical experts and risk analysts to the site of at least eight therapeutic misadministrations. NRC officials say the first of these "event analysis" teams responded in early February to a teletherapy misadministration, although the NRC is keeping names and places anonymous and won't publish individual risk analysis results until the end of the year when they will all be compiled in one report.

The event analysis project originated last year when the NRC was still drafting its rule on quality assurance (QA), and was, according to an NRC document, intended to "help the NRC in determining whether the scope and depth of the proposed rule are adequate." Although the NRC adopted the final rule on quality management and misadministrations in July 1991, and the rule took effect in January, the goals of the event analysis project remain the same.

John H. Glenn, Jr., PhD, chief of the NRC medical, academic, and commercial use safety branch, explains by saying, "The QM rule that was adopted last spring was the child of the basic QA rule. The intention of commission [for the event analysis project] was to take a basic look, asking if there is more needed than the QM rule."

The Society of Nuclear Medicine and the American College of Nuclear Physicians vigorously opposed provisions of the NRC's proposed quality assurance rule, and continue to oppose the final QM rule. SNM and ACNP filed a petition in February asking a federal court of appeals to nullify the regulation and the court is scheduled to hear the case in May.

Dr. Glenn says the event analysis project is not directly related to the QM rule, nor will the project be affected by the SNM and ACNP petition. "This [project] is part of the broader comprehensive look," he says. "We are going to go back to the commission and tell them if further rule makings are needed."

Each event analysis team will include a physician, a medical physicist, a dosimetrist, and a technologist who have expertise in radiation oncology, teletherapy, brachytherapy, or nuclear medicine and radiopharmaceutical therapy, depending on the type of misadministration. (Diagnostic misadministrations of iodine-131 doses greater than 30 milliCuries will be included.)

On the roster of nuclear medicine physicians who will respond to therapeutic radionuclide misadministrations are David F. Adcock, MD, MPH, University of South Carolina School of Medicine; Michael M. Graham, MD, PhD, Scientific Applications International Corp.; and Gregory A. Wiseman, MD, University of Washington Medical Center.

Each team will also include an NRC inspector and a risk analyst. "We use risk analysis extensively in nuclear power plants," says Dr. Rathbun, "Obviously the power plant methodology won't directly apply to medicine, but we're trying to see if we can bring that risk-based approach to medicine."

For the types of accidents investigated, NRC officials expect the risk analysis to identify which are high-probability, which are low-probability, and what consequences each accident could have, judged by the chances for injury, death, or cancer to result.

"We're looking at frequency, we are looking at consequences, and where limited resources might have the most effect," says Dr. Glenn. "We have tried to be sensitive to the criticism that we might be directing resources to events with low consequences." ■

J. Rojas-Burke

Identifying Nuclear Medicine's Practitioners

Who is performing nuclear medicine? The manpower committee of The Society of Nuclear Medicine (SNM) expects to answer that and related questions with its latest survey, preliminary results of which are due to be presented in June at the SNM Annual Meeting in Los Angeles. Publication of the completed survey in *Newsline* is planned for the end of the summer.

Conducted by telephone, the survey is designed to count the professionals in the U.S. who are practicing nuclear medicine either full-time or part-time. Respondents are asked to list the physicians, scientists, and technologists working at each location and to indicate how much of each individual's time is devoted to nuclear medicine. The survey also asks the number of vacancies for nuclear medicine professionals at each location.

To conduct the survey, the manpower

News Briefs

committee targeted about 4585 hospital and outpatient facilities where nuclear medicine is practiced in the U.S. SNM obtained the list from Technology Marketing Group, a marketing research company in Des Plaines, Illinois that compiled the information from the Society's membership rolls and rosters of licensees with the Nuclear Regulatory Commission and state radiation health agencies.

A previous manpower survey, conducted by mail-in questionnaire in 1986, generated a 29% response rate. By far the majority of the respondents were full-time practitioners of nuclear medicine. That survey thus inadvertently missed many radiologists, cardiologists and others who practice nuclear medicine procedures and as a result did not fully represent the specialty of nuclear medicine.

The current census effort achieved a 35% response rate after an initial round of calls by SNM members to chiefs of nuclear medicine or chief technologists, but the data remained biased by limited responses from small-volume departments. By April 1992, part-time telephone operators overseen by SNM Associate Executive Director Virginia Pappas brought the response rate to 50% for nearly every state. At press time, surveyors had reached over 70%.

The manpower committee's goal was to reach at least 70% of the identified nuclear medicine facilities in each state, the minimum acceptable response rate recommended by statistician Jerry Katzoff, who is advising on the census. Schuyler V. Hilts, MD, manpower committee chairman, obtained $950 in additional funding for the survey at the SNM Mid-Winter Meeting, bringing the total cost of the project to about $25,000. ■

Infection Mishaps

(continued from page 14N)

their recommendations for the new rule after discussing the issue with the nuclear medicine physicians at their institutions. The department sent copies of the proposed rule to every hospital in the state and the six nuclear pharmacies, she says. During the month-long comment period after the proposal was posted in the state register, Dr. Linden says the department received no written responses. The regulatory burden of the revisions, she says, "really is trivial," since the department isn't adding new fees or scheduling regular inspections.

The revised rules don't pose problems for Syncor nuclear pharmacies, according to Joe Fery, senior pharmacist at the company's operation in Long Island, New York. "I think it's relatively easy for Syncor to comply. We have always worked with each nuclear medicine department to draft a protocol that complies with their specifications," he says. "Now may be the time to devise a uniform standard."

What is more important than regulatory actions, some nuclear physicians say, is gaining approvals for alternatives to in vitro autologous blood cell labeling. By far the most prominent infection control problem in nuclear medicine is preventing the mistake of giving the wrong person a prepared blood product, Dr. Lull and other nuclear physicians say.

For imaging infections, at least, the problem is obviated by techniques such as labeled monoclonal antibodies, and human nonspecific immunoglobulin G (IgG). The alternative approaches enable physicians to detect infections without drawing blood for labeling. "What we need," says Dr. Lull, "is rapid approval of these technetium-labeled monoclonal antibodies that are widely available in Europe."

Investigators who have pointed to indium-111-labeled leukocyte scintigraphy as the method of choice for detecting some types of infections say that some physicians nevertheless avoid the technique. "I think indium [leukocyte imaging] is under-utilized," says Christopher J. Palestro, MD, a physician at Mt. Sinai Medical Center in New York. A "big negative factor" he says, is that some physicians choose to avoid working with blood if possible. Perhaps equally intimidating is the lengthy and labor-intensive nature of the procedure. If physicians are avoiding leukocyte imaging, for whatever reasons, development of effective alternatives might not only reduce infection risks but also directly improve management of subacute infections and opportunistic infections.

"We just don't label blood in known AIDS patients," says Dr. Marcus of UCLA. She says that her department lacks adequate facilities to work safely when labeling blood samples. Dr. Marcus has secured an Investigational New Drug (IND) approval for clinical trials of a technetium-99m labeled antibody that binds to neutrophils, chemotactic leukocytes that adhere to immune complexes, to image infections. The labeled antibody was developed by Matthew Thakur, PhD, of Thomas Jefferson University, in Philadelphia, Pennsylvania. So far the UCLA investigators have used the agent in 15 patients, including one patient with AIDS, and are enthusiastic about the results. "We think it's one of the most promising ways to solve the problem," says Dr. Marcus.

J. Rojas-Burke