SNP, ACNP Cite Rarity of Problems, Existence of Adequate Safeguards

Opposition Strong to Proposed NRC Quality Assurance Regulations

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"If implemented, these new requirements would constitute unprecedented NRC intrusion into the practice of medicine."

The nuclear medicine community continued to voice its strong opposition to the quality assurance regulations proposed by the Nuclear Regulatory Commission (NRC) during a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in January in Bethesda, Maryland.* "I think there was a unanimous feeling among all the NRC consultants and NRC people present that the proposed regulation, as written, was not workable, would not deter misadministrations, and would increase the cost of nuclear medicine care," said Carol Marcus, PhD, MD, a few days after attending the meeting. Dr. Marcus heads the Nuclear Medicine Outpatient Clinic at the Los Angeles County-Harbor/University of California at Los Angeles (UCLA) Medical Center.

The NRC formally expressed its intention to further regulate use of licensed materials in nuclear medicine last October, when both the Proposed Rule and the Advanced Notice of Proposed Rulemaking were published in the Federal Register. (According to Janet P. Kotra, PhD, technical assistant to Nuclear Regulatory Commissioner Frederick Bernthal, a Proposed Rule is the first step in seeking public input in the possible development of regulations, while an Advanced Notice communicates the NRC's serious intention of adopting some regulation or policy statement on the matter.) The proposed regulations would affect procedures used in ordering, prescribing, and administering radiopharmaceuticals, as well as record keeping, checks on dosages,

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* The Advisory Committee on the Medical Uses of Isotopes includes Chairman Richard E. Cunningham, Nuclear Regulatory Commission; Vincent P. Collins, MD; Sally J. DeNardo, MD; Jack K. Goodrich, MD; Melvin L. Griem, MD; Nilo E. Herrera, MD; B. Leonard Holman, MD; Gerald M. Pohost, MD; Edward W. Webster, PhD; David Woodbury, MD. Consultants are Peter R. Almond, PhD, and Capt. William H. Briner (Ret.) At the meeting were Anthony Tse, PhD; Herbert W. Mower, ScD; James A. Deye, PhD; John Austin; N.L. McElroy; Moody D. Wharam Jr., MD; Norman D. LaFrance, MD; Carol S. Marcus, PhD, MD; Glenn L. Tonnesen, MD; and James L. Ritchie, MD.

The NRC's Advisory Committee on the Medical Uses of Isotopes, left to right: David Woodbury, MD; Melvin L. Griem, MD; Peter R. Almond, PhD; Vincent P. Collins, MD; Edward W. Webster, PhD; non-member Norman L. McElroy, NRC staff; Richard E. Cunningham, Chairman; Gerald M. Pohost, MD; B. Leonard Holman, MD; Jack K. Goodrich, MD; and Capt. William H. Briner (Ret.)

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source strength measurements, and calibration measurements.

According to data collected by the NRC, 27 therapy misadministrations were reported during the period of November 1980 through July 1984. These misadministrations were attributed to such things as arithmetic mistakes, poor handwriting of critical numbers, and differences in oral and written prescriptions. "Three basic themes run through the reports: inadequate training, inattention to detail, and lack of redundancy," the NRC noted. These errors caused administrations of the wrong radiopharmaceutical, the wrong dosage, and, in one reported case, administration of a therapeutic dose to the wrong patient, according to the NRC.

Several Thousand Rads

The NRC also referred to its published report that listed 14 "misadministrations of diagnostic dosages of iodine-131 that lead to doses in the therapy range." In these cases, "patients were administered one to 10 millicuries of iodine-131 with a resulting thyroid dose of several thousand rads." The agency estimates that 10 million diagnostic and 30,000 therapeutic nuclear medicine procedures are performed annually in the United States (US).

"This proposed action is necessary to provide better patient safety and a basis for enforcement action in cases of therapy misadministration," the NRC's Federal Register notice added. "The amendment is intended to reduce the chance and severity of misadministrations."

In response, The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP)† provided the Commission with a joint statement urging the rejection of comprehensive quality assurance requirements while providing recommendations on how to reduce the misadministration of I-131 sodium iodide.

Noting that its views represent those of "the 12,000-plus physicians, scientists, technologists, radiopharmacists and other professionals engaged in the medical and research uses of byproduct material," the joint statements of the ACNP and the SNM are unambiguous. "If implemented, these new requirements would constitute unprecedented NRC intrusion into the practice of medicine," reads the statement. "The extremely low rate of both diagnostic and therapeutic misadministrations provides solid evidence that additional regulations are not needed and the nuclear medicine community has an unparalleled record of protecting patients from misadministrations."

"The claim is made that the NRC, by trying to enforce regulations, is interferring in the practice of medicine," Dr. Kotra said a few days after the January meeting. "That's not my impression of the Commission at all. . . . One of the things the Commission has to consider is that we don't want to penalize the good performers, but to get at those who are operating suboptimally, those who have misused the trust put in them by being an NRC licensee."

Misadministrations Rare

While the SNM and the ACNP agree that the Commission's motivation is sound, they doubt that the Proposed Rule is helpful. For one thing, while misadministrations are serious, all parties agree that they are also rare. Statistics cited in the joint statements of the SNM and ACNP put the annual rate of diagnostic misadministrations of radiopharmaceuticals in the US at one in 10,000, with therapy misadministrations estimated to be one in 18,750 (based on six therapy misadministrations reported from November 1980 through July 1984). These statistics, the Society and College contend, represent a diagnostic misadministration rate "one to two orders of magnitude lower than misadministrations of nonradioactive drugs," and justify eliminating the NRC's reporting requirement for diagnostic misadministrations. Moreover, according to remarks at the meeting by Gerald M. Pohost, MD, of the University of Alabama School of Medicine in Birmingham, Alabama, the mortality rate for misadministrations is about one-tenth a person per million. Opponents of the proposed regulations question whether these statistics can be improved, and if so, at what cost. "Unfortunately, human error is beyond regulation," the College and Society said in their statement.

The joint statement also pointed out that "most diagnostic misadministrations pose no clear harm to patients." Dr. Marcus noted during the January meeting that too much I-131 may destroy a patient's thyroid, an undesirable, but not lethal, outcome.

The existing regulation of nuclear medicine was also highlighted by regulation opponents. Both the ACNP and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have established standards, and existing NRC regulations are also designed to assure quality. The Joint Review Committee on Educational Programs in Nuclear Medicine Technology (JRCNMT) provides national standards for training and education, and the Nuclear Medicine Technology Certification Board (NMTCB), established by the SNM Technologists Section 10 years ago, certifies technologists.

One of the NRC's concerns is to

† Members of the ACNP/SNM working group that developed the statement: David Brill, MD; Capt. William Briner (Ret.); Robert Henkin, MD; John Laude, MD; Letty G. Lutzker, MD; Carol Marcus, PhD, MD; Barry Siegel, MD; Dennis Swanson, MS; and Susan Weiss, CNMT.

have regulations that could result in enforcement actions, and to that end the Commission's proposed additions to its existing rules cover a wide range of nuclear medicine activities with specificity. Concerning the ordering, prescribing, and administration of certain radiopharmaceuticals, the Proposed Rule in the Federal Register stipulates:

- A licensee may not order any radiopharmaceutical of iodine for diagnosis or therapy, or any radiopharmaceutical for therapy, without approval of the authorized user.
- A physician may not prescribe a radiopharmaceutical of iodine for diagnosis or therapy, or any radiopharmaceutical for therapy, without personally examining the patient and the patient's chart, and consulting with the referring physician if reasonably available. Prescriptions must be in writing, and must include the patient's name, the radiopharmaceutical, dosage, and route of administration.
- A licensee may not administer a radiopharmaceutical of iodine for diagnosis or therapy or any radiopharmaceutical for therapy without comparing the compound's label and dosage on hand with the physician's prescription.

Prescriptions and Records

Concerning prescriptions, records, and checks of the medical use for therapy, the Proposed Rule states:

- The authorized user, or a physician under supervision of the authorized user, shall ensure that, if there is a primary care physician, the patient has been referred for a therapeutic clinical procedure that requires the medical use of byproduct material.
- Before beginning treatment, the licensee shall verify that the authorized user or a physician working under supervision of the authorized user has personally made, dated, and signed a written prescription in the patient's chart that identifies the body part to be treated. Any change must be written on the chart, and dated and signed.
- For radiopharmaceutical therapy, the prescription must identify the compound, the amount of activity to be administered, and the route of administration. For brachytherapy, the prescription must also identify the sources of radiation and the total tumor dose. For teletherapy, the prescription must also include the teletherapy unit to be used, the prescribed dose, and the treatment plan.
- Prescriptions and records must be legible and unambiguous.
- The licensee shall instruct all workers involved in the radiation therapy process orally and in writing to request clarification from the prescribing physician if any part of a prescription or other record is unclear, ambiguous or apparently erroneous.

Concerning discrepancies in records and observations, and the administration of dosages, the Proposed Rule requires:

- A licensee may not use byproduct material for medical use if there is a discrepancy in records, observations, or physical measurements that may result in a misadministration. Once the discrepancy is resolved, use may be resumed.
- A licensee shall verify that the prescribed radiopharmaceutical is being administered by comparing the written prescription with the container label.

Concerning sources for brachytherapy and source strength measurements, the Proposed Rule states:

- A licensee shall measure the source strength of sources before first use and annually thereafter. Sources in storage and not being used do not have to be measured, but must be measured before being placed in service again. For sources manufactured and supplied in lots of nominally identical sources, a sample from each lot may be selected rather than measuring each source.
- When performing dose calculations, a licensee may use the source strength reported by the manufacturer rather than using the source strength measured by the licensee.

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While the Proposed Rule is only that—a proposal—Dr. Marcus decided to take the process a step further: As an experiment, she attempted to implement these proposed regulations on October 21, 1987. "I've had three months' experience trying to make that law work. It doesn't work," she said a few days after the meeting.

Retrieving Charts

For one thing, Dr. Marcus told the Advisory Committee in an oral presentation based on her prepared statement, she was forced to abandon ordering I-131 on a patient-by-patient basis as she said the rule requires because it is prohibitively expensive, and she would need another clerk to put in orders and pick up deliveries. Her facility orders at least 50 mCi I-131 every other week, with additional orders as necessary; 10 doses of 5 mCi each cost $250, while one 50 mCi shipment costs $115, she said.

To give the committee members some idea of volume, she told them that last year her facility performed 506 thyroid uptake measurements, 236 thyroid scans, and 58 thyroid

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I-131 treatments. The facility ordered 2.7 Ci of I-131 and 108 mCi of I-123, and her department follows about 200 patients who have been given I-131 therapy doses in the past.

The requirement to review the patient's chart also caused problems for Dr. Marcus. Retrieving charts from the Medical Center's records department is difficult, she said, and some of her patients' charts are in foreign countries.

Physician's Referral Not Always Available

While Dr. Marcus noted that she has always met with the referring physician when necessary, a requirement to do so poses an impossible burden: Some patients simply walk into the clinic without a physician's referral, and a detailed, written referral request can easily take the place of a conference. Sometimes, too, a physical examination of the patient is wholly unnecessary, Dr. Marcus said, especially if she has a surgeon's referral note for I-131 treatment, the operative note, the pathology report, the discharge summary, and the results of laboratory tests, including thyroid hormone levels. "All I'm going to see is a fresh neck scar," she told the Committee.

The regulatory process is now moving to its next phase. Dr. Marcus is one of the persons invited to address the Commission at another meeting to be held in March 1988, a meeting Dr. Kotra expects to provide an airing of a wider spectrum of opinion. Afterward the Commission and staff will study the data and public comments and decide what to do—to adopt the current proposal, to formulate a new Proposed Rule that would start the review process all over again, or to adopt a policy statement, a position paper that lacks regulatory authority. Dr. Kotra added that the process could be completed in a few months or, more typically, could take about two years. "Absent major rethinking, most likely this rule will go forward, or something that looks like it," she said. "The Commission intends to do something."

Radiation Therapy

The current proposal would not only affect nuclear medicine, but it would also have a great impact on radiation therapy. Concerning physical measurements of the patient, the Proposed Rule states:

- A licensee shall check dose calculations for accuracy before 50% of the prescribed dose has been administered. The check must provide assurance that the final treatment plan will provide the dose prescribed in the patient's chart.
- Manual dose calculations must be checked by someone who did not perform the original calculations. Computer-generated dose calculations must be checked by someone who did not enter the patient data or prescription into the computer.
- In a medical emergency, a physician can provide the prescribed treatment without performing the checks listed above, but a notation of this must be made on the patient's chart and the licensee is to perform the checks as soon as practicable.

Concerning teletherapy and full calibration measurements:

- Full calibration measurements must include determination of output plus or minus 3% for the range of field sizes, range of distances, and selection of beam modifying devices (for example, trays, wedges, and the stock material that is used for making compensators and boluses) for medical use. An independent check of the output determined from this calibration is required within one month. The independent check must be performed by a teletherapy physicist who did not perform the full calibration and made using a dosimetry system other than the one used to measure the output during the full calibration.
- A licensee shall check dose calculations for accuracy before 20% of the prescribed dose has been administered.
- Manual dose calculations must be independently verified, and computer-generated calculations must be checked by someone other than the person who originally entered the data into the computer.
- A licensee shall make a weekly accuracy check of daily arithmetic calculations in patient charts.
- If the patient's dose calculations include parameters or parameter values that fall outside the range of those measured in calibrating the teletherapy unit, the licensee shall make a physical measurement of the dose rate to be administered. This measurement must be made before 20% of the prescribed dose has been administered.
- In a medical emergency, a physician can delay checking dose calculations or physical measurements, but a notation must be made on the patient's chart and the checks shall be performed as soon as practicable.

$360,000 Per Misadministration Avoided

In his remarks to the Advisory Committee, Glenn Tonnesen, MD, from Falls Church, Virginia, estimated that it would cost his practice roughly $4,000 to be in total compliance with the new rule. If there are roughly 1,000 cobalt machines in the US, each spending $4,000, then the proposal would cost about $4 million, he said. Assuming the regulations could reduce the 27 misadministrations by half to 14, then it would cost about $360,000 per misadministration avoided—money that could be better spent, Dr. Tonnesen said, for state-of-the-art equipment that could save more lives directly.

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