COMMENTARY

NRC WORKSHOP PARTICIPANTS DISCUSS THE PART 35 PETITION AND THE QA RULE

Most Nuclear Regulatory Commission (NRC) medical workshops consist of NRC telling licensees what to do. The NRC workshop held in Oakland, California, July 18–19, 1989 differed in that NRC opened the workshop to extensive and intensive discussion both during the meeting itself and in numerous informal gatherings over the two-day period and that a very strong contingency of nuclear medicine and nuclear pharmacy people attended. Most of the discussion centered around the shortcomings of the 10 CFR Part 35 revision, which went into effect April, 1987 and why The Society of Nuclear Medicine and the American College of Nuclear Physicians (ACNP) are so supportive of their June 5, 1989 Petition for Rulemaking Change (see *Newsline* Sept. 1989, p. 1296). NRC displayed a very reasonable attitude toward the petition at the meeting, and SNM/ACNP is hoping for a very positive decision on it in the near future. California, which is an agreement state, is separately considering the petition as well.

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John E. Glenn, PhD, chief of the NRC's medical, academic, and commercial use safety branch, was very understanding about the problems caused by the Part 35 revision, but he stressed that any deviation from the regulations or from a license condition would need to be submitted first to the NRC for a variance or an amendment. In essence, the "regs are the regs" until they are changed. Dr. Glenn emphasized that decisions affecting patient welfare (such as those which arise from Part 35.300 restrictions) would be dealt with in a very timely manner, such as in minutes to hours if that were required. He took a very sensible approach and was very credible. He is new to his present position at NRC and is studying our problems very carefully.

The NRC presentation on the proposed quality assurance (QA) regulations was given by John Telford, leader of the rulemaking section in the NRC's regulation development branch. The QA rule, as presented, engendered much acrimonious debate, and no small amount of the anger was due to the fact that NRC has continually refused to back up its assumption of significant risk to the public health and safety from misadministrations with any scientific data or scientifically validated risk assessment, a pre-condition for action that is inferred from the Atomic Energy Act.

NRC made the decision to write a QA rule in response to the Commission's statement that "there's room for improvement." In times of cost containment, this is not a particularly meaningful statement. All areas of human endeavor have room for improvement. A responsible administrator knows he is obliged to estimate the hazard of leaving something alone, the cost of making it better, and the cost of the benefit that would result. The NRC should also realize that "he who pays the piper calls the tune," and the guy with the fat wallet these days is the Health Care Financing Administration (HCFA). HCFA wants more for less and prefers not to discuss quality. NRC wants perfection at any cost but has no money. It is disappointing that NRC has not had the insight to sit down with HCFA and "cut a deal." For example, an extra technologist in nuclear medicine may save one misadministration a year because personnel are not so pressured, but it may cost one emergency room nurse, which results in, say, three deaths that year unless HCFA ups the ante on nuclear medicine procedure reimbursement so that a hospital can afford the extra tech *and* the nurse.

When the Commission decided to write a QA rule, it could have looked for precedent at the Food and Drug Administration (FDA), which has had a single, mandatory, misadministration reporting rule in effect for many years. Misadministrations of red blood cell transfusions must be reported *only if they cause death.* Ten million red cell transfusions a year result in about 13 deaths from misadministrations. No vindictive "enforcement action" is taken by FDA. Data are released on request to the scientific community, and analyses are published in the scientific literature. *It is unlikely that the total number of deaths from misadministration of all radiopharmaceuticals throughout the entire history of nuclear medicine in the United States is any greater than the yearly rate of deaths from misadministra-*

tion of red cell transfusions. However, NRC apparently has no interest in FDA precedent in misadministration reporting.

The next mistake NRC made was to purposefully exclude SNM and ACNP participation in the rulemaking. No nuclear medicine expertise was represented, and the rulemaking attempts have been characterized by a profound lack of understanding of the manner in which medicine is practiced.

Once the Joint Commission on Accreditation of Health Care Organization's (JCAHO) QA manual, Examples of Monitoring and Evaluation in Diagnostic Radiology, Radiation Oncology, and Nuclear Medicine Services, was published in 1988, it was hoped that NRC would adopt JCAHO's more enlightened philosophy toward medical QA. However, this was not the case.

Once the NRC committment to write a QA rule began, it went inexorably forward because a Senior Executive Service Contract mandated that it be out in two years. No matter whether they were needed, no matter whether they were good, it was "regs for regs sake" in two years, period. Some of those individuals required to write the QA rule have used a "Nuremberg argument" to explain their involvement, and thereby denied responsibility. It is difficult for a regulatory agency to maintain credibility when leadership does not truly understand the issues and staff does support its actions. Members of SNM and ACNP present at Mr. Telford's talk wondered at the travesty wrought on NRC's mandate for medicine as written in the Atomic Energy Act of 1954: "Sec. 104. MEDICAL THERAPY AND RESEARCH AND DEVELOPMENT. (a) The Commission is authorized to issue licenses to persons applying therefore for utilization of facilities for use in medical therapy. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and protect the health and safety of the public."

No one from the nuclear medicine community listening to Mr. Telford's presentation doubted that the new QA rule would do other than permit NRC regions to hassle nuclear medicine licensees even more than they are doing at present. A recent comment by a Region IV NRC inspector, "This is the year of Nuclear Medicine. We're going to get you guys!" aptly summarizes the attitude of some within the NRC toward nuclear medicine. Hopefully the new leadership at NRC (Commissioner Carr became Chairman on July 1, 1989) will find "room for improvement" in NRC's attitude.

Other NRC presentations at the workshop included "Medical Licensees and the Decommissioning Rule," "Managing a Radiation Safety Program: NRC Perspective," "CFR Part 35 Brachytherapy Requirements," "Escalated Enforcement Policy," "Training Requirements for Professional and Ancillary Staff," and "Performance Evaluation Factor Program." Scott Dubé, from the Queen's Medical Center in Hawaii, gave a delightful talk on "Patient and Room Preparation for Liquid and Implant Therapy;" Jerry Bushberg, PhD, from the University of California, Davis gave an excellent presentation on "Managing a Radiation Safety Program: Licensee's Perspective," and David Price, MD, of the University of California, San Francisco, gave a superb exposé on "Chairing a Radiation Safety Committee."

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SNM Manpower Survey

In the January, 1989 issue of *The Journal of Nuclear Medicine, Newsline* featured an article entitled Survey of Nuclear Medicine Physicians, Scientists, and Facilities — 1986. We regret that we failed to properly acknowledge the Federated Council of Nuclear Medicine Organization's (FCNMO) support of the manpower survey.

When FCNMO was in the process of disbanding in 1986, Howard J. Dworkin, MD, chief of the nuclear medicine department, William Beaumont Hospital, then president of The Society of Nuclear Medicine, negotiated with representatives of FCNMO, and subsequently the SNM received the funding for the survey. The SNM wishes to express appreciation to FCNMO for its support of this project.

The SNM also would like to give special thanks to B. Jerald McClendon, United States Public Health Service, Bureau of Health Professions, for the many hours he spent analyzing the statistics for the survey and developing the draft of the report. ■