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Mr. Samuel J. Chilk
Secretary
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Re: COMPREHENSIVE QUALITY ASSURANCE IN MEDICAL USE AND A STANDARD OF CARE, 52 Fed. Reg. 36949 (October 2, 1987)

This letter responds to the Nuclear Regulatory Commission's (NRC) request for comments on the Advanced Notice of Proposed Rulemaking (ANPR) pertaining to quality assurance in the medical use of materials licensed pursuant to the Atomic Energy Act and Energy Reorganization Act. The ANPR states that the major goal of the Commission proposal is to develop a regulatory regime which will ensure that no misuse of licensed materials will occur. The Commission's proposals will not meet that goal and should not be adopted.

The Office of the Chief Counsel for Advocacy was established under the Pub. L. No. 94-305, 90 Stat. 668 (1976) (codified at 15 U.S.C. § 634a), to represent the views of small businesses before Federal agencies. 15 U.S.C. § 634c. The Commission's proposal would affect a substantial number of small entities. Approximately 35% of the licensees other than private practice physicians are small businesses. See 50 Fed. Reg. 50241, 50242 (Dec. 9, 1985). The NRC estimates that 90% of the private practice physicians are small businesses under its size standards. An equivalent number of licensees would be affected in states in which the NRC has ceded its licensing authority. See infra text at 2. Thus, a substantial number of small entities would be affected by the proposal.

To achieve a level of no misuse of licensed material, three major modifications to the current regulatory scheme are proposed: (1) establishment of a comprehensive quality assurance program by medical use licensees; (2) redefinition of misadministration; and (3) implementation of a standard of care for licensees. The stated goals of the ANPR are admirable but the Commission has not uncovered any evidence that the medical use of licensed material poses an undue risk to public health

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and safety. Under such circumstances, Commiss[illegible]egulations, adjudicatory decisions, and judicial review of [illegible]mmission action do not mandate the proposed actions. [illegible]rmore, the proposed actions would impose significant [illegible]a licensees without reducing the risk associated with the [illegible]dical use of licensed material. Finally, the proposed actions would increase the likelihood of litigation between physicians and patients. The Commission should examine less burdensome alternatives which: (1) impose stricter training and licensing requirements of nuclear medical technicians; (2) require legible written prescriptions; and (3) focus on promulgating safe regulatory procedures.

I. Statutory Foundation and Regulatory Structure

The Atomic Energy Act, as amended, 42 U.S.C. §§ 2011-2296, (AEA) prohibits the manufacture, production, transfer, acquisition, or ownership of byproduct material without a license. 42 U.S.C. § 2111. Byproduct material is any material made radioactive through the use of fission except for plutonium and certain isotopes of uranium. Id. at § 2011(e). The NRC issues licenses to those applicants who can demonstrate the ability to comply with NRC regulations and not pose an undue risk to the public health and safety. Id. at § 2111. The NRC has issued 2,500 licenses to use byproduct material for medical uses.

The AEA also permits states with radiation regulatory programs compatible with the NRC's to regulate byproduct material. Twenty-nine states have issued about 5,000 licenses for medical use of byproduct material.

The underlying tenet of Commission regulation of byproduct material is the principle of "as low as reasonably achievable" (ALARA). The concept requires licensees to take every reasonable action to prevent unnecessary radiation exposures. Medical licensees are required to implement a radiation safety program to maintain ALARA for the licensees' employees. 10 C.F.R. § 35.20. No requirement currently exists to maintain an ALARA program for patients.

One branch of the ALARA concept is the misadministration of radiopharmaceuticals which are drugs marked with a radioisotope. Misadministrations can occur in four ways:

1. The incorrect radiopharmaceutical is given to the patient

2. Radiopharmaceuticals are given to the wrong patient.

3. The correct pharmaceutical is given to the correct patient but the route of administration is incorrect.

4. Everything is correct but the radiation dosage received by the patient exceeds the prescribed dose by more than fifty percent.

Id. at § 35.2. Diagnostic misadministrations by their very nature do not present as a great a danger to the patient as therapeutic misadministrations. It is unclear what, if any, long-term effects will result from diagnostic misadministrations.

In order to maintain ALARA and prevent misadministrations, the NRC prescribes the training and experience needed by physicians before they are permitted to use byproduct material. However, the Commission does not prescribe any training, other than basic safety training received as part of the ALARA program, for nurses and technicians.

The Commission's regulations require licensees to follow certain procedures such as use of syringe and vial shields, dose measurement and calibration devices, and radiation survey equipment. The current regulations do not provide for a quality assurance program for diagnostic uses of byproduct material.

II. The Proposed Changes

The NRC is considering modifying the regulations for medical use of byproduct material in order to ensure that misadministrations will never occur. Three specific changes are mentioned as a path to achieve the goal.

The most significant change is the establishment of a comprehensive quality assurance program for diagnostic uses of byproduct material by one of two methods. One option would require the Commission to identify and adopt through rulemaking the elements of a quality assurance program which would guarantee the elimination of misadministrations. The other method would lead to the imposition of a performance requirement under which licensees would establish a quality assurance program, with the specifics left to the discretion of the licensee, that would provide an absolute assurance that no misadministrations would occur.

The second proposal involves possible modifications to the definition of misadministration. Although the Commission does not explicate the specific changes that it might consider, the most likely change would extend the ALARA concept to patients and define any unnecessary exposure as a misadministration.

Implicit in this change would be a reduction of the margin of error in radiation exposures from 50% to some significantly smaller percentage such as the 10% currently used in therapeutic misadministrations. Second, any prescription by a licensee which did not result in a correct diagnosis or exposed the patient to more radiation than needed to obtain a correct diagnosis would be unnecessary exposures in violation of ALARA and a misadministration.

Finally, the Commission is investigating the possibility of promulgating a standard to define the acceptable medical use of byproduct material. The ANPR requests comments on the need for the NRC to develop such a standard and, if the need exists, the type of standard the Commission should adopt.

The goal sought by the Commission is admirable. Unfortunately, the modifications proffered by the NRC will not achieve the goal of eliminating misadministrations. Moreover, the Commission's decisions and court cases do not require a guaranty against all risk arising from radiation. Finally, the attempt will impose significant costs on licensees and reduce the availability of nuclear medicine to the public.

III. The proposed modifications are not required by Commission policy or current data

A. The AEA does not require absolute assurances of safety

The AEA authorizes the NRC to promulgate regulations which the Commission determines are necessary to "protect the public health or to minimize danger to life or property." 42 U.S.C. § 2201(b). In Power Reactor Development Co. v. International Union of Electrical Workers, 367 U.S. 396 (1961), the Court held that the Commission may issue a license so long as the Commission was satisfied that the licensee could provide a reasonable assurance of safety to the public. Id. at 414-15. An absolute assurance of safety was not required and this view has been reiterated in Commission decisions, see, e.g., Louisiana Power & Light Co., 21 N.R.C. 471 (1985); Maine Yankee Atomic Power Co., 6 A.E.C. 1000 (1973), and in the ALARA concept. The courts often have rephrased the standard as "no undue risk to public health or safety." See, e.g., Union of Concerned Scientists v. NRC, 829 F.2d 103 (D.C. Cir. 1987); Westinghouse Electric Corp. v. NRC, 598 F.2d 759 (3d Cir. 1979); North Anna Environmental Coalition v. NRC, 533 F.2d 655 (D.C. Cir. 1976).

The Commission should not now modify its regulations unless evidence exists that the current standards do not provide a reasonable assurance of safety in diagnostic uses of byproduct material.

B. No evidence demonstrates an undue risk exists from diagnostic uses of byproduct material

The diagnostic application of byproduct material is performed through ingestion, inhalation, or injection. Different radiopharmaceuticals are used to perform different diagnostic studies. The NRC estimates that ten million diagnostic procedures are performed each year.

In 1986, the NRC's Office for Analysis and Evaluation of Operational Data (AEOD) published a report of diagnostic misadministrations. The NRC found only 14 misadministrations occurred during the period 1982 to June, 1986 and each one involved the substitution of radioiodine for some other pharmaceutical for use in thyroid scans. The NRC estimates that 500,000 scans are performed each year. The Commission determined that the probability of a misadministration is 6 in 1,000,000. The NRC is considering methods to reduce the probability to zero.

AEOD never studied the misadministration for other procedures, other radiopharmaceuticals, or different methods or courses of administration. The NRC studied only 5% percent of the administrations during the time period of the study. Yet from this, the Commission is considering imposing significantly stricter standards on all diagnostic uses. The probability assessment by AEOD of thyroid scan misadministrations, even if it supports a finding of undue risk from the use of radioiodine for thyroid diagnoses, cannot be extrapolated to support a similar conclusion for all radiopharmaceuticals, all diagnostic procedures, and all routes of administrations.

The report also fails to provide a basis for modifying the definition of misadministration. The Commission would have to determine that the current definition does not provide a reasonable assurance of public health and safety. If so, the Commission might have a valid basis for redefining misadministrations. However, the evidence gathered by the Commission suggests that a very minor problem exists with respect to iodine-based thyroid scans.

Instead of promulgating a comprehensive quality assurance program for all diagnostic uses of radiopharmaceuticals and interjecting the concept of ALARA into the definition of misadministration, the NRC should develop regulations to reduce the incidence of error in the use of radioiodine which is the only potential problem area evidenced by the Commission's own

data. The Commission also could then undertake a study of all diagnostic uses of all byproduct material. The evidence from such a study would establish whether a more comprehensive regulatory revision is needed.

IV. The proposed changes will not achieve the stated goal of the ANPR

The stated goal of the ANPR is to ensure that misadministrations will never occur. While all licensees should strive for perfection in their operations, perfection cannot be legislated or regulated. The imposition of a quality control program may reduce human error but will not eliminate it. A review of the AEOD report demonstrates that a quality assurance program will not reach the NRC's goal.

The AEOD found that half the misadministrations occurred due to miscommunication between the physician and the technologist who administered the radiopharmaceutical. In these cases, the physician requested a thyroid iodine scan but the technologist believed that the physician meant a whole-body scan using iodine. A quality assurance program which requires the confirmation of the physician's request would reduce miscommunications but would not eliminate them. When the technologist calls for confirmation, the physician might not be available or the language used by the technologist in asking for confirmation might not remove the uncertainty. In short, no quality assurance program will ever eliminate the communication failures that resulted in half the misadministrations.

The other half of the misadministrations have no easily identifiable cause although it appears that the majority of them resulted from a lack of knowledge by technologists of dose requirements for elementary diagnostic procedures. According to the AEOD report, the number of misadministrations would have been reduced if technologists had recognized that a dose application did not make sense given the procedure requested. The AEOD report's finding of lack of knowledge does not provide support for a quality assurance program; rather it suggests the need for better training and, possibly licensing, of technologists.

The efficacy of quality assurance programs in private clinic and physician offices is an open question. For the individual practitioner, a quality assurance program would be meaningless. If the physician administers the radiopharmaceutical, no person exists for confirmation. If a technologist performs the administration, the confirmation process could prove disruptive to the physician's relationship with other patients due to constant interruptions. A better

alternative might require licensees in private practice or in clinics to provide legible, written instructions to the technologist. Like a quality assurance program, this option will not eliminate misadministrations but would reduce them without the severe impacts of such a program.

V. The proposals would increase the costs of medical services without eliminating misadministrations

The NRC did not specify particular procedures that would be included in a comprehensive quality assurance program. The NRC proposed a basic quality assurance program for radiation therapy. One of the key elements of that program is independent verification of radiation dose by someone other than the person who originally calculated the radiation dose. Presumably, the independent verification of radiation dose also would be a cornerstone of a comprehensive quality assurance program for diagnostic uses.

As a practical matter, independent verification would create significant problems for nuclear medical specialists. Unlike radiation therapy which is performed in hospital settings, diagnostic procedures are often performed in physician offices or clinics. Hospital nuclear medical units have sufficient staff for meaningful independent verification. Physicians in private practice may not have the staff to provide independent verification or the physician may perform the administration.

There may not be any person capable of performing the independent verification and the physician rechecking the calculations defeats the purpose of the verification. In other cases, a meaningful independent verification may require the physician to hire a radiation technician to perform the independent recalculations.

The additional costs of more technicians to perform meaningful verifications would be an excellent idea if the costs would reduce the number of misadministrations. However, the AEOD report showed that the major problem was not miscalculation but inadequate knowledge by technicians and miscommunication between physician and technician. Verification would raise costs to physicians and patients without guaranteeing the elimination of misadministrations.

VI. There is no record supporting a formal regulatory standard of care

The Commission is seeking comments on the possibility of imposing a standard of care on medical use licensees which would define what constitutes good nuclear medical practice.

We believe that the proposal would not reduce misadministrations, and could place the NRC definition in conflict with those promulgated by state courts.

Another serious consideration is the impact of the NRC's imposition of a standard of care on insurance costs and malpractice litigation. The NRC's proposal would create a conflict between the traditional provision of state remedies for malpractice with the NRC's mandate to regulate the safety of medical use of byproduct material.

The conflict was addressed in Silkwood v. Kerr-McGee, 464 U.S. 238 (1984). The Court first noted that the issues presented by the case "affects both the States' traditional authority to provide tort remedies to their citizens and the Federal Government's express desire to maintain exclusive regulatory authority over the safety aspect of nuclear power." Id. at 248. The Court then examined Kerr-McGee's contention that the award of punitive damages was preempted by the regulatory authority in the AEA. The Court, after examining the legislative history of the AEA and the Price-Anderson Act (the act that limits the liability of NRC licensees in the case of an extraordinary nuclear occurrence), concluded that Congress did not preclude citizens from utilizing state tort law to obtain redress of injuries arising out of NRC-licensed activities. Id. at 256.

The imposition of an NRC-imposed standard of care in a common-law matter would create uncertainty in many areas. Confusion would reign in the courts as they attempted to determine whether to apply their standard or the NRC's standard.

The situation would be exacerbated by the common law principle that regulatory violations are negligence per se. Under the proposed redefinition of misadministration, states would then be left with a dichotomy -- their common-law standards of negligence and the new stricter NRC standards, violations of which would be considered negligence. Insurance companies probably would contend that their policies were not written to cover much stricter determinations of negligence. This would lead to litigation over coverage in addition to any litigation against physicians by patients for malpractice. The NRC's proposal would increase the cost of malpractice insurance and might force some insurance companies to abandon coverage of nuclear medical specialists. For these reasons, we believe that this proposal will result in the reduced availability of nuclear medical services. We suggest that the NRC leave standards of care to the states and the agency should focus on the development of regulations for the safe application of radiopharmaceuticals.

VII. Conclusion

The AEA authorizes the NRC to regulate the use of byproduct material to protect the public health and safety. The NRC's policy with respect to the regulation of medical uses of such material recognizes the dilemma of protecting the public and patients from the radiation hazards associated with the medical use of such material without unduly interfering with the practice of medicine. The NRC's proposal would adversely affect a substantial number of small entities, including almost all of the private practice physician licensees, without providing any additional safety benefits to patients or the public.

The NRC and the courts do not require absolute guarantees of safety. Rather, the AEA and NRC only demand that the licensed activity present no undue risk to public health and safety. The ANPR sets absolute safety as the regulatory end. While the goal is admirable, the probability of eliminating the already miniscule error rate through any regulatory program borders on the impossible.

Instead of attempting to achieve the unachievable, the NRC could require stiffer training criteria for radiation technicians. The Office of Nuclear Material Safety and Safeguards rejected this option; the AEOD report provides sufficient support to increasing the training and licensing requirements for technicians. The imposition of such requirements would go a long way toward eliminating the problems found in the AEOD report without imposing an entirely new regulatory scheme. Moreover, the NRC should consider requiring legible written prescriptions to alleviate some miscommunication. Finally, the NRC should focus on regulating radiation hazards; it should leave standards of care and concomitant tort liability questions to the states. These alternatives would provide additional protection without imposing significant costs on licensees or reducing the availability of nuclear medical services.

Yours very truly,

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