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If no answer, 356-1616

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January 30, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

ATTN: Docketing and Service Branch

RE: Proposed amendments to 10 CFR part 35 "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material"

Dear Sir,

I wish to comment on the proposed rule cited above.

I am a practicing nuclear pharmacist with over 12 years of experience. I work in a nuclear medicine department in a large tertiary care hospital. Since my experience is almost totally radiopharmaceutical-related, I shall limit my comments to radiopharmaceutical misadministration/events.

I strongly believe that the rules currently contained in 10 CFR part 35 are sufficient and adequate and that additional rules are not necessary. I would like to support my belief with a few examples.

Diagnostic misadministrations are relatively rare and always benign. At my hospital, the misadministration rate over the last 8 years has been approximately 0.02%. This is comparable to the misadministration rate of 0.01% previously estimated by the NRC (McElroy NL: NRC Reports on Misadministrations and Unannounced Inspections; 1986). In contrast, the misadministration rate for therapeutic drugs used in hospitals is, at best, two orders of magnitude higher. For example, a recent study found a medication error rate (excluding wrong-time errors) of 1.6% (Jozefczyk K et al: Medication Errors in a Pharmacy-Coordinated Drug Administration Program. Am J Hosp Pharm 43:2464-2467, 1986). Earlier studies found medication errors occurring with as many as one in six doses of medication (e.g., Barker KN: The Effects of an Experimental Medication System on Medication Errors and Costs. Am J Hosp Pharm 26:388-397, 1969). Unfortunately, many of these medication errors result in increased morbidity, prolonged hospital stays, and occasional mortalities. Such sequelae are just not associated with diagnostic misadministrations!

As stated above, diagnostic misadministrations do not result in non-stochastic effects. The stochastic risk of late effects (e.g., induction of cancer) is exceedingly small, approximately equaling that from background radiation exposure for one year or from smoking one pack of cigarettes. This risk is thus similar to other voluntary and involuntary risks to which the general public is commonly exposed and is thousands of times lower than the risk of "spontaneously" developing cancer.

As stated by NRC, almost all misadministrations are caused by human error. Proper training of personnel and following policies and procedures are essential components of good practice. I don't believe that new rules are needed, however; compliance with existing rules will achieve as much success as possible--more rules will probably not result in any substantial improvement because of the ever-present human error and cases of non-compliance. For example, NRC states that the most common cause of radiopharmaceutical therapy misadministrations is "dosage was not assayed." Clearly, 10 CFR 35.50 and 35.53 require that each radiopharmaceutical dosage be measured prior to medical use. Thus, if compliance with existing rules is achieved, a substantial fraction of misadministrations might be avoided.

In proposed 35.35, NRC would require that a prescription be made prior to medical use. State laws regarding the practice of medicine and the practice of pharmacy already require that a prescription or medication order must be made prior to drug dispensing and administration. I would suggest that, instead of a new rule, NRC interacts with state boards of medicine and pharmacy, to educate and encourage them regarding enforcement in this area. Furthermore, 10 CFR 35.53 (c) (3) requires records of the prescribed dosage and 35.2 defines misadministrations in context of differing from the prescribed dosage; thus, the necessity of making a prescription prior to medical use is an inherent requirement of current rules.

In proposed 35.35 (a) (1), NRC would require assurance that medical use is indicated for the patient's medical condition. This judgement is clearly an integral part of the practice of medicine. But medical judgement is outside of the scope of expertise of NRC. It is, however, well within the scope of state boards of medicine and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In fact, the appropriateness of diagnostic studies or therapy is a "hot topic" for JCAHO standards and inspections. Hence I would suggest that NRC, instead of pursuing rules for which NRC cannot judge compliance, work with organizations such as state boards of medicine and JCAHO to ensure that these organizations are evaluating and enforcing compliance.

Lastly, no matter how many policies and procedures exist, no matter how well trained personnel are, and no matter how conscientious personnel are, misadministrations will continue to occur even in a "perfect" nuclear medicine department. For example, in the last two years, one-half of the misadministrations occurring in our hospital were not the fault of nuclear medicine--rather, the referring physician ordered the nuclear medicine procedure for the wrong patient. Additional NRC rules cannot and will not prevent this type of misadministration.

In summary, I believe that the proposed rules are totally unnecessary with regard to radiopharmaceuticals. I base my belief on the following:

1. The rates for misadministrations are already very low, at least two orders of magnitude lower than the rates for therapeutic drugs used in hospitals.
2. Diagnostic misadministrations do not result in any observable or measurable non-stochastic effects in patients.
3. Stochastic risks from diagnostic misadministrations are exceedingly small, typically less than the risks incurred from many voluntary and involuntary activities in daily life.
4. A large fraction of misadministrations may be preventable simply by ensuring compliance with existing rules (e.g., measuring dosages before administration).
5. A substantial fraction of misadministrations are caused by factors outside the control of nuclear medicine personnel (e.g., referring physicians request procedures for the wrong patients).

I believe that the proposed rules will thus have negligible impact on the incidence of radiopharmaceutical misadministrations.

NRC states its desire (responsibility) to protect the health and safety of patients. If NRC wants to significantly influence current problems, I recommend that it "quit spinning its wheels" with more unnecessary rules and instead devote its resources to productive interactions with state boards of medicine and pharmacy and organizations such as JCAHO which are in a much better position to regulate and enforce medical practice.

Thank you in advance for your consideration of my comments.

Sincerely,

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JAP/pd