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American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

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September 3, 1999

Greta Joy Dicus, Chairman
Nuclear Regulatory Commission
Washington, DC 20555

DOCKET NUMBER
PROPOSED RULE PR 20, 32 + 35
(63FR43516)

Dear Chairman Dicus:

The Society of Nuclear Medicine and the American College of Nuclear Physicians would like to take this opportunity to express their concern with the Commission's program to rewrite the medical use regulations contained in 10 C.F.R. Part 35. When the Part 35 rewrite was announced in 1997, the Commission directed the staff to produce a risk-based (later changed to risk-informed), performance-based rule. At the same time, the Commission agreed to adopt rulemaking procedures that provided additional opportunities for stakeholder input, vowing to institute a "partnership process" with the regulated medical community.

As the Commission prepares to consider staff's proposed final rule, we find that the sentiments we expressed in our written comments on the proposed rule are still equally true today:

Despite the effort expended, we must regretfully conclude that the proposed is not substantially superior to the rule it would replace. Additionally, it satisfies neither the concerns the nuclear medicine community has expressed over the years, nor the directions the Commission issued to its staff when this process began because the proposed rule, like the existing one, imposes a wide variety of expensive, unnecessary and unjustifiable requirements on diagnostic nuclear medicine. Virtually every review of the safety of diagnostic nuclear medicine shows it to be an extremely safe medical modality (safer, indeed, than over-the-counter drugs such as aspirin). Yet the NRC seems unwilling or unable to regulate it in a manner that is meaningfully related to its risks. The absence of any public health justification for such an approach, coupled with the increasingly difficult financial constraints under which medicine operates means that this approach simply cannot continue.

When the Society and the College, joined by the Council on Radionuclides and Radiopharmaceuticals and the Nuclear Energy Institute, called on the Commission to conduct the risk assessment implicit in providing a sound scientific basis for any resulting rule, the Commission declined. It should be noted that during the rulemaking process, "risk-based" became "risk-informed"; whichever term is used, both start with a quantitative risk assessment. Risk-informed rather than risk-based regulation is becoming commonplace, and we support the Commission's desired use of it. However, typical risk-informed regulation uses social, economic and political considerations to lessen, rather than increase, regulatory control. Of particular

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importance, conventional risk analysis is used to estimate the occurrence of adverse health effects, and has output units of probability (for stochastic processes like carcinogenesis) or severity (for non-stochastic processes like cataractogenesis), not dose. Thus, what is called risk analysis in this rulemaking actually is not. In the absence of a valid risk assessment, we believe that the Commission's approach is a wholly unsupported and dangerous way to regulate, for the costs imposed on the health care system by needless Commission regulation inevitably mean that some other needed service - and the public's health - will suffer.

While we believe that the proposed new Part 35 is fundamentally flawed and a serious disservice to the public, we single out for your attention the following specific issues:

1. Notification following medical events (35.3045). We continue to oppose as unnecessary any requirement that a referring physician or patient be notified of a medical event.

2. Exposure to fetus or nursing child (35.3047). We continue to believe that this provision is counterproductive, creating false illusions of hazard and, often, inappropriate blame. In the end, it will require a pregnancy test before every procedure on a woman of childbearing age, thus increasing costs, or encouraging the use of other procedures without reporting requirements.

3. Written directives (35.40(a)). State law, created in consultation with qualified medical and pharmacy professionals, adequately regulates the use of prescriptions.

4. Use of the Regulatory Guide. It appears that instead of using the authority under 10 CFR 30.34(e) to impose requirements to cover unusual or new circumstances, the Commission is using this authority to create a new level of more restrictive regulation. The Regulatory Guide process is outside the purview of the Administrative Procedure Act and is not subject to OMB review; it also thwarts the "general license" provisions of Part 35, rendering it meaningless.

We conclude by restating our fundamental position, as stated in our 1998 comments on the proposed rule:

> We believe that both the scientific record and the long history of the safe use of diagnostic nuclear medicine procedures compel a conclusion that the health and safety of the patients, the public, and workers can be well protected solely by specifying training and experience requirements for authorized users in conjunction with the radiation safety requirements of Part 20.

It disappoints us greatly that the considerable time and expense devoted to the Part 35 rewrite by the Commission and interested stakeholders have yielded so little. The Commission's original direction was sound; the execution of it has failed completely.

Members of the Society of Nuclear Medicine and American College of Nuclear Physicians are available to meet with you at your convenience to resolve these important matters in a mutually agreeable fashion. We will contact you to set up a meeting. In the meantime if you have any questions, please contact William R. Uffelman, Director of Public Affairs, Society of Nuclear Medicine at 703-708-9773 or by email at wuffelman@snm.org.

Very truly yours,

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