



Advancing Molecular Imaging and Therapy

February 3, 2012

Secretary

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

#### VIA ELECTRONIC SUBMISSION

**RE: Nuclear Regulatory Commission; Docket ID NRC-2011-0269; Incorporation of Risk Management Concepts in Regulatory Programs; Request for Comments**

Dear Sir/Madame:

The Society of Nuclear Medicine (SNM) appreciates the opportunity to respond to the Commission's request for comments as posted in the *Federal Register* notice on November 22, 2011 regarding the incorporation of risk management concepts in regulatory programs. SNM's more than 17,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings and leading advocacy on key issues that affect molecular imaging and therapy research and practice.

#### ***Common Understanding and Usage of Terms***

The SNM does not believe there is a common understanding of the terms 'risk-informed', 'performance-based' and 'defense-in-depth' among the medical stakeholder community. There may be a general impression of what these terms mean, but even less so of how the medical stakeholder should construct their program given this approach. SNM recommends NRC define these terms, and give detailed concrete examples to support the explanations. The examples currently cited in this docket are not very helpful because they are related exclusively to the nuclear power industry.

#### ***Lessons Learned From Risk-Informed and Performance-Based Initiatives***

Citing the example above from nuclear medicine, risk (i.e. dose) –based release criteria, as opposed to the previous non-risk (i.e. activity) –based release criteria, for radionuclide therapy patients has made the management of such patients more rational, safer, and more cost-effective. Reducing the need for hospital stays provides patients, their families and caregivers psychological and emotional benefits of having the patient with them and of lowering their health care costs. It also provides societal benefits by reducing the direct economic costs, and commitment, of medical resources required to retain the patient in a hospital. Less prescriptive regulations are an advantage; however SNM suggests NRC develop guidance for licensees on how to develop their program such that it is risk-based in the minds of both the applicant and the regulator.

#### ***Lessons Learned From Deterministic Regulatory Actions***

The deterministic approach provides a program with a common denominator. While reasonable for a large percentage of applicants, it may not always be best suited for some leading them to spend an inordinate amount of time documenting activities with very little risk that should have been of little concern to the detriment of other areas that are of greater importance. Therefore, SNM believes this approach to be unnecessarily onerous and expensive for licensees to implement, without serving public safety any better than or as well as risk-based regulations.

### ***Integration of Traditional Deterministic Approaches***

A deterministic approach may be reasonable for some aspects of a program, however NRC must clearly define what is meant by 'deterministic'. This approach may be augmented by a more risk-based approach for those areas that vary widely from licensee to licensee.

### ***Challenges to Accomplishing the Goal of a Holistic Risk Management Regulatory Structure***

In many ways, a prescriptive regulation is easier to follow and a large amount of documentation can be provided to support this. Therefore, for a holistic approach to be successful, guidance must be provided to the licensee to assist him/her in developing the most successful safety program that places the appropriate emphasis in the right places. SNM also recommends NRC more clearly define what is meant by a 'holistic' risk management regulatory structure.

### ***Time Period Needed for Transition***

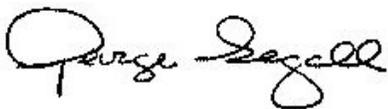
SNM believes a transition to a risk management regulatory structure would presumably require a major re-write of the relevant regulations – 10 CFR 35.75 in the case of the medical use of isotopes – and subsequent adoption by licensees. Such a major undertaking for the NRC and its licensees would require upwards of 5 years.

### ***Areas Likely to Benefit From Transition***

Based on a review of inspections, the areas most challenging for licensees to address and place personnel (both workers and patients) at the most risk for exposure are likely those that will benefit the most from a transition to a risk management regulatory approach. SNM believes a risk-informed, performance-based approach would be particularly useful in the context of medicine and the medical use of isotopes.

The SNM is pleased to provide comments to the NRC on the incorporation of risk management concepts in regulatory programs. Should you have any questions, please contact Sue Bunning, Director of Health Policy and Regulatory Affairs, [sbunning@snm.org](mailto:sbunning@snm.org) or (703) 326-1182.

Sincerely,

A handwritten signature in black ink that reads "George Segall". The signature is written in a cursive, flowing style.

George Segall, MD  
President

CC: Fred Fahey, DSc  
Gary Dillehay, MD  
Munir Ghesani, MD  
Virginia Pappas  
Sue Bunning