

Gallagher, Carol

Subject: FW: SNM Comments on NRC Risk Management Concepts
Attachments: SNM comments on Risk Management Concepts.pdf

From: Bunning Sue [mailto:SBunning@snm.org]
Sent: Friday, February 03, 2012 9:08 AM
To: Pangburn, George
Cc: Merrill Janette
Subject: SNM Comments on NRC Risk Management Concepts

16

11/22/2012

77 FR 72220

George,

Thank you so much for taking time out of your schedule to join us at our Government Relations Committee meeting. I hope you found it helpful.

As you know, we are past the comment period and cannot formally submit to the docket. I am therefore attaching the SNM comments for your consideration.

The major messages are that we do not believe our members understand these terms and so more guidance with respect to understanding these terms and how to develop radiation safety programs in nuclear medicine using this model would be helpful. Deterministic, more proscriptive approaches are easier with which to comply (just follow the rules) but a more risk based approach in conjunction with a performance based review is more preferable as long as it is accompanied with proper guidance.

Feel free to call if you have any questions. Thanks again.

Sue

Sue Bunning
Director, Health Policy & Regulatory Affairs
SNM | Advancing Molecular Imaging and Therapy
1850 Samuel Morse Drive
Reston, VA 20190
P: (703) 326-1182
C: (703) 430-4100
F: (703) 708-9777
www.snm.org

RECEIVED

FEB 15 PM 2:40

FILES, REGULATORY AFFAIRS

From: Merrill Janette
Sent: Friday, February 03, 2012 8:58 AM
To: Bunning Sue
Subject: SNM Comments on NRC Risk Management Concepts

Hi Sue:

Attached is the pdf of the SNM comments on the NRC Risk Management Concepts.

Janette

Janette Merrill, MS CHES

SUNSE Review Complete
Template = ADM-013

1

ERFDS = ADM-03
Add = C. LUI (CXL)

Associate Director, Health Policy & Regulatory Affairs
SNM | *Advancing Molecular Imaging & Therapy*
1850 Samuel Morse Drive
Reston, VA 20190
P: (703) 652-6760
F: (703) 708-9777
www.snm.org

The premier nuclear medicine and molecular imaging event is coming to Miami Beach. Live a little. *Learn a lot.* **SNM 2012 Annual Meeting.**

Reserve your spot now. The **3rd Multimodality Cardiovascular Molecular Imaging Symposium and In Vivo Preclinical Imaging Workshop** are currently accepting registrations.



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

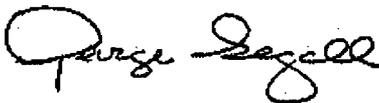
SNM believes a transition to a risk management regulatory structure would presumably require a major re-write of the relevant regulations – 10 CFR 35.75 in the case of the medical use of isotopes – and subsequent adoption by licensees. Such a major undertaking for the NRC and its licensees would require 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 or (703) 326-1182.

Sincerely,



George Segall, MD
President

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