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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
US Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemakings and Adjudications Staff

Re: RIN 3150-AI26, Medical Use of Byproduct Material—Amendments/Medical Event Definitions, Revision 1

Dear NRC Rulemakings and Adjudications Staff:

As a broad scope medical licensee with very active nuclear medicine therapy and brachytherapy programs, we are primarily concerned about two issues. The first is the length of the comment period for this draft rule. Revision 1 to this rule was distributed on February 22, 2008, just days before the end of the comment period (February 26, 2008), with significant changes to the text of the original draft language, distributed on February 8, 2008. These changes are significant enough that they warrant additional time for public review and comment. We recommend that the comment period be extended.

The second issue that is of concern is the definition of a medical event. As written in §30.3045(a), the language defines a medical event as the failure to prepare a written directive, when one was required, for any type of therapy, not just permanent implant brachytherapy. We support the concept of written directives and understand their importance. However, not completing a written directive is not an incident worthy of being defined as a medical event. Especially since summaries of medical events are periodically reported to Congress, and inclusion of such minor violations could do two things: needlessly expand the number of incidents reported to Congress; and, potentially detract from the more significant medical errors. It is also important to note that the changes to the definition are inconsistent with the original recommendations made by the ACMUI to leave the criteria for modalities other than permanent implant brachytherapy unchanged. We recommend that §30.3045 be rewritten to clarify the definition of a medical event as it applies solely to permanent implant brachytherapy, leaving the criteria for other modalities unchanged.

We appreciate the opportunity to comment on this issue.
Sincerely,

Conrad Nagle, M.D.
Corporate Chief, Diagnostic Imaging Services

Janice Campbell

Janice Campbell, Ph.D.
Corporate Medical Physicist, Nuclear Medicine

Cheryl Culver Schultz

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