

**PR 35**  
**(73FR45635)**

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## PUBLIC SUBMISSION

**Docket:** NRC-2008-0071

Medical Use of Byproduct Material - Amendments/Medical Event Definitions

DOCKETED  
USNRC

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**Comment On:** NRC-2008-0071-0018

Medical Use of Byproduct Material--Amendments/Medical Event Definitions

October 21, 2008 (1:19pm)

**Document:** NRC-2008-0071-DRAFT-0024

Comment on FR Doc # E8-18014

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

### Submitter Information

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Chapel Hill, NC, 27516-7131

**Organization:** Sherouse Systems, Inc.

### Redacted Comment

Regarding RIN 3150-A126,

I am a Radiation Oncology Physicist with significant experience with various techniques for "seed" brachytherapy of the prostate. As such I wish to speak to what may be unforeseen issues that would arise from the proposed rule.

Let me preface by saying that I am in wholehearted support of the NRC's intent to clarify regulations that are currently very difficult to apply to prostate brachytherapy. In my own practice I have seen both poorly-executed implants which the current regulations failed to identify as misadministered, and implants that were consistent with the typical variation of practice that could have been tagged as MEs by an overly-literal application of the current regulations. Both kinds of ambiguity detract from our focus on providing consistent quality care.

Template = SECY-067

SECY-02

While I applaud the intent, I believe the specific solution is in some ways no better, and may in some scenarios be worse. I have detailed one such scenario in a separate comment. History has shown clearly the inadequacy of a simple prescribed dose Written Directive. I suspect that for every scenario in which the prescribed dose has proven problematic an analogous scenario could be imagined in which the prescribed total strength could fail similarly to define intent. Indeed, the ground would be fertile for even worse problems because in the current era of real-time intraoperative planning we at least know with certainty the intended dose from the start but typically do not determine the total source strength until the procedure is already underway. Perhaps the proposed strength-based Written Directive would have been an improvement 10 years ago when a significant percentage of practice used the Seattle-style preplanned, preloaded needle approach, but the trend today is clearly toward image-guided intraoperative planning and delivery.

I would encourage the NRC to consider bringing the regulations more into line with the actual medical practice. Nearly all discussion in the practice literature of prostate brachytherapy dose is cast in terms of dose-volume relationships, such as the percent volume of the prostate that receives the prescribed dose (so-called V100) and the minimum dose that is received by at least of 90% of the prostate (D90). A set of such constraints, in combination with a fail-safe like the 3 cm criterion in the proposed rule, would allow for implants to be objectively assessed for quality using the same metrics that are intergrated into clinical practice and relevant literature.

## Rulemaking Comments

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**From:** Carol Gallagher  
**Sent:** Tuesday, October 21, 2008 11:14 AM  
**To:** Rulemaking Comments  
**Subject:** Comment on Medical Use of Byproduct Material Proposed Rule  
**Attachments:** sherouse2.pdf

Attached for docketing is a comment from George Sherouse on the above noted proposed rule (73 FR 45635) that I received via regulations.gov on 10/20/08.

Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by TWMS01.nrc.gov  
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Content-Type: application/ms-tnef; name="winmail.dat"  
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