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## PUBLIC SUBMISSION

**Docket:** NRC-2008-0071

Medical Use of Byproduct Material - Amendments/Medical Event Definitions

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

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

October 21, 2008 (1:19pm)

OFFICE OF SECRETARY  
 RULEMAKINGS AND  
 ADJUDICATIONS STAFF

**Document:** NRC-2008-0071-DRAFT-0023

Comment on FR Doc # E8-18014

### Submitter Information

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### 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

I will focus in this comment on the application of the proposed rule in the setting of one particular commonly-used delivery technique. In this technique the typical scenario is as follows, once a patient has been identified for prostate brachytherapy:

- The patient's urologist performs a "volume study" in the urology office and reports to the radiation oncology department the patient's apparent prostate volume. This is typically assessed using ultrasound to measure a nominal "height," "width" and "length" of the prostate from which a volume is computed by assuming the shape is a regular ellipsoid.

- The AU writes a Written Directive for a specific dose to the prostate, understood to be the nominal minimum peripheral dose to a volume that encompasses the anatomic prostate plus a small margin of additional tissue surrounding the prostate, assuming certain constraints of dose variation over the treatment volume and certain other dose constraints to the rectum and urethra. That is to say, the Written Directive gives a shorthand for a more complex set of desired dose-volume constraints on the ultimate treatment plan. The Written Directive serves as the sole prescription for the treatment.

- About a week before the procedure the radiation oncology staff orders seeds by looking up a total Air Kerma Strength (AKS) for the implant from a nomogram, and ordering that total AKS plus 10% to allow for normal uncertainty, at a per-seed AKS that is between 0.4 and 0.6 U, depending on the total prostate volume. I want to emphasize that in this technique there is no pre-plan done before the seeds are ordered and the total AKS ordered is determined solely from a lookup table based on the urologist's approximate volume measurements. I also want to emphasize that it is impossible for the staff to proceed before a prescription is provided by the AU.

- On the day of the implant an intraoperative treatment planning system is used to capture images of the patient's prostate in the actual treatment position, a customized treatment plan that meets all of the AU's dose-volume constraints is developed in the operating room while the patient is under anesthesia, and that plan is then delivered.

- At the end of the procedure a Written Procedure is updated to reflect the plan as developed and delivered on the day.

This technique when properly executed by an experienced treatment team yields excellent implants.

It is not at all unusual for the variance of the total AKS delivered to the patient to be different by more than 20% from the total AKS indicated by the nomogram or from the total AKS ordered for the case. Indeed, this variation is expected. There are many reasons for this, the top 3 being:

- The volume of the prostate used for ordering seeds is only approximate and subject to a great deal of uncertainty.

- The nomogram represents only an approximation of the total AKS required to treat a prostate of the expected volume.

- The details of the optimal implant, including the optimal total AKS required to achieve the target dose pattern, are influenced by both the specific shape of the patient's prostate and the treatment position of the patient during the implant, neither of which is accounted for in the pre-treatment phase.

Extra seeds are routinely ordered to accommodate these uncertainties in order to avoid the very difficult scenario in which the uncertainties might cause there to be too little total AKS available to perform an adequate implant on the day. In that event the case must be aborted and rescheduled or else the patient must be underdosed, either scenario having undesirable effect on the patient.

I have a concern that under the proposed rules either 1) we would have to report Medical Events on a substantial percentage of our patients, perhaps one third, because of the quite expected variation between the estimated total AKS indicated by the nomogram and the total AKS indicated by the more detailed intraoperative treatment plan, or 2) we would need to divorce our initial treatment prescription from the Written Directive, follow our procedure as described, but have the AU prepare the Written Directive only seconds before the beginning of the source placement, that being after the patient has been anaesthetized and the intraoperative treatment plan has been completed. I am concerned about the tremendous amount of

counterproductive  
paperwork required in the first scenario in order for us to report the customization  
of the  
treatment plan as a Medical Event. I am equally concerned in the second scenario  
about the  
potential for introducing new points of failure into the planning and delivery  
process, specifically  
about having a prescription that is separate from the Written Directive and about  
having no time  
in the process for the Written Directive to be subjected to quality assurance review  
before the  
source placement begins.

Perhaps this could be clarified in the final rule.

## Rulemaking Comments

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**From:** Carol Gallagher  
**Sent:** Tuesday, October 21, 2008 11:00 AM  
**To:** Rulemaking Comments  
**Subject:** Comment on Medical Use of Byproduct Material Proposed Rule  
**Attachments:** sherouse.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 OWMS01.nrc.gov  
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