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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)

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Comment on FR Doc # E8-18014

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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.

I am very concerned by the lack of care and rigor exercised in both the current and the proposed regulations, and particularly in the supporting material of the current proposal, with regard to the quantities involved. Specifically, the terms "activity" and "strength" are used apparently interchangeably and without clear definition. The use of the term "dose" is also somewhat sloppy.

Three quantities having to do with the amount of radiation emitted by a radioactive

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SECY-02

material are
of interest in the context of sealed source brachytherapy:

- "Contained activity" is a measure of the number of radioactive disintegrations per unit time that occur in a quantity of radioactive material. This quantity is significant in Federal regulation as related to transportation of radioactive materials. If a sealed source were to be ruptured in a transportation accident, contained activity is the appropriate measure of just how much radioactivity could be released into the environment.

- "Apparent activity" is a variant of contained activity that applies to sealed sources. The apparent activity is reduced by an amount that depends on the inherent filtration of the sealed source. Apparent activity has the somewhat backhanded definition of being that unfiltered amount of material that would produce the same rate of radioactive decay as can be measured from the filtered source. Apparent activity is the unit of radioactivity traditionally used for the calculation of radiation dose to tissue from sealed-source brachytherapy. That usage has been deprecated in clinical practice by the adoption of the TG-43 dosimetry protocol.

- "Air kerma strength" is a measure of the amount of energy that is emitted per unit time by a sealed source, independent of the number of disintegrations it undergoes. Air kerma strength is determined by direct measurement using NIST-traceable detectors and forms the basis of the TG-43 dosimetry protocol that has been the AAPM's recommended standard for clinical brachytherapy dosimetry for many years.

The terms "activity" and "strength" alone, as used in the supplementary information regarding the proposed rule changes are ill defined and not helpful. Indeed, the current CFR 35 has instances of use of each of those ill-defined terms (see for instance "activity" in 10 CFR 35.2406 and "total source strength" in 10 CF 35.40) that should be clarified.

I would call for more rigorously correct usage of these terms. I would further call for the terminology in revised regulations to be consistent with the recommended clinical practice. Sealed brachytherapy sources should always be labeled with their Air Kerma Strength for regulatory purposes, as they should be for clinical practice. Requiring licensees to use different

units for different purposes in handling the same sources creates a safety hazard by increasing the possibility that the wrong units will be used in determining patient dose.

Rulemaking Comments

From: Carol Gallagher
Sent: Tuesday, October 21, 2008 11:27 AM
To: Rulemaking Comments
Subject: Comment on Medical Use of Byproduct Material Proposed Rule
Attachments: sherouse3.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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From: Carol Gallagher <Carol.Gallagher@nrc.gov>
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>
Date: Tue, 21 Oct 2008 11:27:16 -0400
Subject: Comment on Medical Use of Byproduct Material Proposed Rule
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