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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

(8)

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001,
ATTN: Rulemakings and Adjudications Staff
Docket # NRC-2008-0071
RIN 3150-AI26

Comments on the Part 35 Preliminary Draft Language, (February 21, 2008), Revision 1

I wish to submit comments for your consideration regarding the proposed amendments will also change the criteria for defining a medical event for permanent implant brachytherapy from dose based to activity based.

A general comment: Allowing only five days to notify and comment on many changes being proposed is inadequate. There have been significant, maybe unintentional, changes that are beyond the scope of addressing changes in the definition of medical event for permanent implant brachytherapy. The entire rewrite of § 35.3045(a) is confusing and convoluted.

Written Directive – §35.40
35.40(b)(6)(ii)
Change "the number of sources and *nominal* activity per source implanted" to "the number of sources and *total source strength* implanted".
The ACMUI was consistent in using total activity or total source strength to describe the implanted dosage and also avoid the use of the term "dose". The word "nominal" introduces another potential term that needs definition and possible confusion. Does it mean average, median, or what? The suggest change avoids this problem and fulfills the stated intention of the ACMUI; and the term is consistent with the requirements of 35.40(b)(6)(i). The NRC suggested change creates an unneeded difference in total activity specification with absolutely no added benefit.

§ 35.3045(a) Report And Notification Of A Medical Event.
The latest revision to 35.3045(a), "*A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared....*" has created an added criteria for what is a medical event. It would make any situation where a written directive was required, but not provided, a reportable "medical event." This may not have been the intention of NRC staff but this change makes a medical event applicable to ALL uses requiring a written directive (I-131 therapy, etc.), not just permanent brachytherapy. This added criteria was never discussed by the ACMUI or the Subcommittee that addressed the changes to the definition of medical event for brachytherapy permanent implants.

The words "if a written directive was not prepared" need to be struck from the proposed revision of 35.3045(a). It should state as follows: "(a) A licensee shall report any as an *a medical* event any administration requiring a written directive or any event, except for an event that results from patient intervention, in which—"

The NRC in §35.40 already has a requirement for a written directive prior to administration. There has been no evidence to support the need to make a violation of this requirement a medical event. This also sets an unnecessary precedent for any violation of the written directive regulations as a medical event. The preamble to these drafted rules gives the wrong impression that this was a recommendation of the ACMUI.

Template = SECY-067

SECY-02

A suggestion for further clarification of §35.40 as it applies to permanent implant brachytherapy might be to revise §35.40(a) to "A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed or sealed implant byproduct material or any therapeutic dose of radiation from byproduct material."

§35.3045(a)(1) Report And Notification Of A Medical Event.
(A) An administration of a wrong radioactive drug containing byproduct material ~~or the wrong radionuclide for a brachytherapy procedure.~~ The strikeout should not be added because this item refers to unsealed radiopharmaceuticals, and the suggested addition is not relevant and not substantiated by any evidence of medical events where the wrong radionuclide used in a permanent implant.

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration ~~or by use of the wrong applicator in a brachytherapy procedure.~~ The strikeout should not be added because this item refers to unsealed radiopharmaceuticals, and the suggested addition is not relevant to radiopharmaceutical therapies or to a permanent implant.

The terminology "if the administration had been carried out" implies a medical event will be based on a hypothetical situation or assumption rather than factual criteria. The intent of the proposed rule would not be changed if this phraseology were deleted wherever it occurs in the rules.

§35.3045(a)(2) - Report And Notification Of A Medical Event.
The ACMUI was very explicit that the final written directive upon which a medical event was to be assessed occurred at the time the "patient is released from licensee control." This section uses the term "preimplantation" which is distinctly contrary to this recommendation. A recommendation is to remove the term "preimplantation" wherever it occurs in §35.3045(a)(2) and replace with, "the written directive at the time the patient is released".

I appreciate the opportunity to comment and hope that you will find these comments constructive for this rulemaking process.

Sincerely,

Ralph P. Lieto, MSE
Advisory Committee on Medical Uses of Isotopes, Member
February 26, 2008

Rulemaking Comments

From: LietoR@trinity-health.org
Sent: Monday, March 03, 2008 3:16 PM
To: Rulemaking Comments
Cc: EML1@trinity-health.org
Subject: RIN 3150-AI26. - Part 35 Preliminary Draft Rule Language
Attachments: Comments-Part 35 Preliminary Draft-PermImplantBrachy022608.doc; Mime.822

Importance: High

** High Priority **

I am resending this submission per request & because I did not receive notice of receipt.
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Please confirm receipt.

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