

Rulemaking Comments

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From: Mike\_Stephens@doh.state.fl.us  
Sent: Friday, November 07, 2008 8:25 AM  
To: Rulemaking Comments  
Subject: RIN 3150-AI26  
Attachments: FLCommentsNRCPpropseRule73fr45635(MedicalUse).pdf

DOCKETED  
USNRC  
November 10, 2008 (10:45am)  
OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Dear Sir:  
Please find an attached pdf file with our comments on RIN 3150-AI26 also found in 73FR45635 "Medical Use of Byproduct Material - Amendments/Medical Event Definitions."

Please contact me should you have trouble opening this file.

Sincerely

MikeS

*Michael N. Stephens*

Bureau of Radiation Control

(850)-245-4266

Fax (850) 487-0435

Visit our Web Site: <http://www.doh.state.fl.us/environment/radiation/>

How are we doing? Please take our survey: <http://www.doh.state.fl.us/environment/radiation/survey.htm>

*Mission: To promote and protect the health and safety of all people in Florida through the delivery of quality public health services and promotion of health care standards.*

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If



Charlie Crist  
Governor

Ana M. Viamonte Ros, M.D., M.P.H.  
State Surgeon General

November 7, 2008

Secretary  
Attn.: Rulemaking and Adjudications Staff  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Sent via e-mail only to:  
[Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov)

RE: RIN 3150-A126  
(73FR45635 – Medical Use of  
Byproduct Material – Amendments/  
Medical Event Definitions)

Dear Mr. Secretary:

Thank you for the opportunity to comment on the proposed rule RIN 3150-A126 (73FR45635- Medical Use of Byproduct Material-Amendments/ Medical Event Definitions).

The Florida Bureau of Radiation Control agrees with the proposed rule changes to section 35.40(b) and 35.40(c) regarding written directives. As with any therapeutic procedure, a written directive by an authorized user before a brachytherapy implant procedure is critical to identifying the intended treatment. We also agree with the requirement that authorized user's document information regarding the actual treatment received after the permanent implant procedure and before the patients leave the post-treatment recovery area.

The Bureau also agrees with the proposed changes to 35.3045 regarding reporting and notification of medical events regarding permanent brachytherapy implants. As with any therapeutic procedure requiring a written directive, failure to prepare a written directive, where one is required, is a serious failure in the licensee's quality control/quality assurance program which may pose a potential significant health and safety implication.

Finally, the Bureau agrees with the compatibility designations of Cat C for 35.3045, Cat D for 35.40(c) and Cat H&S for 35.40(b).

Thank you for the opportunity to comment on these proposed rules. If you have any questions, please contact me at (850) 245-4266.

Sincerely,

A handwritten signature in black ink that reads "Michael N. Stephens".

Michael N. Stephens  
Program Consultant  
Bureau of Radiation Control

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