



Iowa Department of Public Health
Promoting and Protecting the Health of Iowans

Gerd W. Clabaugh, MPA
Director

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

November 18, 2014

US Nuclear Regulatory Commission
Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)

Re: Iowa Department of Public Health (IDPH) Agreement State Comments to proposed rule revisions
RCPD-13-001 (10 CFR Parts 30, 32, and 35)
Docket ID NRC-2014-0030

The Iowa Department of Public Health Agreement State program has reviewed the July 21, 2014 Federal Register notice (NRC-2014-0030) which contained the proposed revision to 10 CFR Part 35. IDPH offers the following comments for review by the NRC.

1. The Iowa Department of Public Health Agreement State program supports all comments as submitted to the NRC by the Board of Organization of Agreement States on November 18, 2014.

2. Section 35.3045 Report and Notification of a Medical Event

Paragraph (a) (2) of this section describes new separate criteria for reporting MEs involving permanent implant brachytherapy. The criterion in Item 4 defines an ME as an absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site that exceeds by 50 percent or more of the absorbed dose to that tissue based on the preimplantation dose distribution approved by an AU.

IDPH has concerns that this definition will make it difficult for licensees to determine if an ME has occurred in the course of clinical practice. This definition also makes it nearly impossible for regulators to independently determine if the licensee is appropriately classifying and reporting ME's. In an effort to better understand the ability of our licensees to define an ME based off of these proposed definitions, IDPH consulted with a medical physics group who would be required to report ME's for permanent implant brachytherapy.

Item (4) - Specifically regarding prostate seed implants, the MP group reported that the normal tissue located within the treatment site would be the urethra, and at their medical center the urethra is not contoured in the post-planning process, as that would require placement of a catheter in order to visualize the urethra on the CT image. Also, based on the pre-planning ultrasound images with a catheter in place, the MP group indicated that the urethral volume is typically 1 cc or less. This would make it impossible for 5 cc of contiguous urethra to receive a dose 50% greater than the pre-implantation dose approved by the authorized user. It appears that licensees may not routinely acquire the imaging information necessary to do this assessment. Even with imaging information, the example of the urethra in prostate implant

brachytherapy indicates that this definition may not allow for a medical event to be classified when surrounding tissues do not comprise 5 cc of contiguous tissue.

Adopting an absorbed dose based criterion for evaluating dose to structures that are even more difficult to contour than the prostate may limit the licensee's ability to assess for ME's using this criterion. If the proposal outlined in Item (2) to move to total source strength rather than absorbed dose when assessing for an ME due to the placement of seeds outside the treatment site is a result of clinical difficulty in evaluating absorbed dose and D90 in a post-plan due to contouring difficulties, then the use of absorbed dose as outlined in Item (4) should also be reconsidered.

If you have any questions, please feel free to contact me or Randal S. Dahlin of my staff at 515-281-0419 or randal.dahlin@idph.iowa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Angela Leek", with a stylized, cursive script.

Angela E. Leek, Chief
Bureau of Radiological Health
(515) 281-3478
angela.leek@idph.iowa.gov

From: [Leek, Angela \[IDPH\]](#)
To: [RulemakingComments Resource](#)
Cc: [Dahlin, Randal \[IDPH\]](#); [Wardrobe, Leo \[IDPH\]](#); [Sharp, Ken \[IDPH\]](#)
Subject: Iowa Agreement State Comments - RCPD-13-001 (10 CFR Parts 30, 32, and 35) - Docket ID NRC 2014-0030
Date: Tuesday, November 18, 2014 12:32:49 PM
Attachments: [Proposed 10CFR35 rulemaking comments IA.pdf](#)

Please find our Iowa Department of Public Health Agreement State comments regarding RCPD-13-001 (10 CFR Parts 30, 32, and 35) - Docket ID NRC 2014-0030.

Thank you,

Angela Leek, MS

Bureau Chief | Bureau of Radiological Health | Division of ADPER & EH | Iowa Department of Public Health | 321 E. 12th Street | Des Moines, Iowa 50319 | Office: 515-281-3478 | Fax: 515-281-4529 | angela.leek@idph.iowa.gov

Promoting and Protecting the Health of Iowans

This email message and its attachments may contain confidential information that is exempt from disclosure under Iowa Code chapters 22, 139A, and other applicable law. Confidential information is for the sole use of the intended recipient. If you believe that you have received this transmission in error, please reply to the sender, and then delete all copies of this message and any attachments. If you are not the intended recipient, you are hereby notified that any review, use, retention, dissemination, distribution, or copying of this message is strictly prohibited by law.