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TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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DAVID L. LAKEY, M.D.
COMMISSIONER

August 10, 2011

Josephine Piccone, Director
Division of Intergovernmental Liaison
and Rulemaking
Office of Federal and State Materials
and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Docket ID NRC-2008-0175 Opportunity to Comment on Preliminary Proposed Rule Language for Medical Use Regulations (FSME-11-044)

Dear Ms. Piccone:

Below are comments regarding the preliminary proposed rule language for medical use regulations.

1. In §35.65, under the heading of "Authorized for calibration, transmission, and reference sources," subpart (a) states that "Byproduct material authorized by this provision shall not be: (1) Used for medical use as defined in §35.2; or ...." In §35.2, medical use is defined as, "Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user."

   The problem with this statement is that the subject heading includes "transmission" sources, which are exclusively used to "intentionally deliver radiation from these sources to the patient" and image the patient's body; resulting in data images that provide quantifying attenuation characteristics unique for that patient. The transmission images once blended with raw patient images will result in cleaner diagnostic images. However, radiation delivery from transmission sources must always be delivered under the supervision of an authorized user, and such transmission irradiation is always used with positron emission tomography (PET) cameras, either by use of a "transmission" byproduct source or an attached CT scanner, and occasionally these sources will be used within traditional gamma cameras.

   It is suggested that §35.65(a) be changed to read: "(a) Byproduct material authorized by this provision, except transmission sources, shall not be: (1) Used for medical use as defined in § 35.2 ...."

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2. Concerning §35.290 relating to training for imaging and localization studies. Training is required in the elution and preparation of radiopharmaceuticals from generators, but not in the handling and use of positron radiopharmaceuticals. Improper handling of positron radiopharmaceuticals is a health and safety issue due to the higher energy radiation of the radionuclides being used and potential for greater exposure through repeated handling. It is suggested that the following training requirements for the use of positron emitting radionuclides be added to §35.290:

   (d) In addition to the training and experience requirements of §35.290(a) - (c), for the use of positron emission tomography (PET) radionuclides, the licensee shall require that the authorized user has:

      (A) completed 24 hours of work experience specific to the use of PET radionuclides consistent with §35.290(c)(1)(ii); and

      (B) a written attestation statement specific to the use of PET radionuclides for diagnostic imaging.

We appreciate the opportunity to comment on the preliminary proposed medical use rule. If you have questions about our comments, contact Barbara Taylor at Barbaraj.Taylor@dshs.state.tx.us or 512-834-6770, ext. 2010.

Sincerely,

Barbara Taylor, Manager
Radiation Policy, Standards and Quality Assurance Group
Division of Regulatory Services
Department of State Health Services

Rulemaking Comments

From: Gallagher, Carol
Sent: Thursday, September 01, 2011 3:53 PM
To: Rulemaking Comments
Subject: FW: TX Response Ltr to FSME-11-044
Attachments: TX Rspns Ltr FSME-11-044 NRC Prelim Prop Part 35_Cmnts 8-10-2011 BT.doc

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From: Bhalla, Neelam
Sent: Wednesday, August 10, 2011 2:17 PM
To: Gallagher, Carol
Subject: FW: TX Response Ltr to FSME-11-044

Hi Carol, here is a comment letter that came from the Texas, Dept of Health. The comment is on the preliminary proposed rule language that we posted on the Federal Rulemaking Web site at http://www.regulations.gov under Docket ID NRC-2008-0175 (in (ADAMS) Accession Number ML111390420). Please handle it. Thanks.
neelam

From: Perez,Monica (DSHS) [mailto:Monica.Perez@dshs.state.tx.us]
Sent: Wednesday, August 10, 2011 9:45 AM
To: Bhalla, Neelam
Cc: Taylor,Barbaraj (DSHS); Piccone, Josephine
Subject: TX Response Ltr to FSME-11-044

Attached is the Texas Department of State Health Services, Radiation Control Program, response letter to FSME-11-044, regarding preliminary proposed rule language for medical use regulations.

Thank you,

Monica Perez
Rule Development Program
Radiation Group
Policy, Standards, and Quality Assurance Unit
Division for Regulatory Services
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