August 3, 2010

Michael S. Gossman, M.S., DABR
Tri-State Regional Cancer Center
Medical Physics Section
706 23rd Street
Ashland, KY 41101

SUBJECT: RESPONSE TO LETTER REQUESTING INTERPRETATION OF U.S. NUCLEAR REGULATORY COMMISSION (NRC) REGULATIONS

Dear Mr. Gossman:

I am responding to your letters to James Lynch of Region III and the Advisory Committee on the Medical Uses of Isotopes (ACMUI), dated April 8, 2010 and April 13, 2010, respectively, requesting an interpretation of sections of Title 10 of the *Code of Federal Regulations* (10 CFR) pertaining to calibration of sealed source brachytherapy implants in general and for prostate implants specifically.

In your letter, you state that you disagree with the contention of some hospitals in the State of Kentucky that a licensee may rely on the vendor assay to satisfy output and activity level of the radionuclide source prior to implantation. You also state that you disagree with the contention of these hospitals that they are not required to purchase equipment necessary to perform these calibrations in-house, since they rely on vendor assay. In addition, you state that your review of 10 CFR 35.630 concluded that a dosimetry system must be in place in-house regardless of the existence of a vendor assay, and that the person qualified to perform those checks must be registered with the "State Office" or with the NRC as an Authorized Medical Physicist (AMP). You indicate that your review of section 35.432 concluded that any measurement must be done in accordance with the accepted practice defined by the American Association of Physicists in Medicine (AAPM), with an AMP attesting to it by professional signature. In support of your position, you cite a 2008 AAPM publication that states that third-party services do not remove the responsibility of an institutional medical physicist to perform these verifications.

It appears that your concerns relate to manual brachytherapy procedures permitted under 10 CFR Part 35, Subpart F, "Manual Brachytherapy." As required in section 35.432(a)(1) in that subpart, before the first medical use of a brachytherapy source, a licensee must determine the source output or activity using a dosimetry system that meets the requirements of section 35.630. Section 35.630(a) requires that a licensee must have a calibrated dosimetry system "available for use" that meets certain conditions.

These regulations require a licensee performing in-house calibrations to have a calibrated dosimetry system <u>available for use</u>; however, they do not require the licensee to <u>purchase</u> a dosimetry system. Furthermore, with regard to your conclusion that reliance on vendor calibration of manual brachytherapy sources is no longer permitted by NRC regulations following the 2008 publication of the Report of the AAPM Low Energy Brachytherapy Source Calibration Working Group, although the AAPM recommendations may not condone user

reliance on vendor assay, and compliance with AAPM recommendations may constitute good practice, such compliance is not required by NRC regulations.

Additionally, with regard to your conclusion that calibration measurements of manual brachytherapy sources must be performed by an AMP, we note that the only duty of an AMP designated in 10 CFR Subpart F is calculation of the activity of strontium-90 sources for ophthalmic treatments, as described in §35.433(a). Although it may be considered good practice for an AMP to perform other tasks associated with manual brachytherapy procedures, NRC regulations do not require this.

You also conclude that calibration measurements of manual brachytherapy sources must be performed in accordance with the accepted practice defined by the AAPM with an AMP attesting to this by professional signature. While §35.432 requires a licensee making its own measurements, source manufacturer, or calibration laboratory accredited by AAPM to use published protocols currently accepted by nationally recognized bodies, there is no requirement for use of a specific protocol, such as one provided by the AAPM, or for an AMP to provide an attestation.

Changes to NRC regulations would be needed via a rulemaking in order to institute the requirements you described. Opportunities for public participation in the rulemaking process are described on NRC's website at http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html.

For further information or for questions, please contact Mr. Michael Fuller, Team Leader of the Division of Materials Safety and State Agreements' Medical Radiation Safety Team at (301) 415-0520, or by email at Michael.Fuller@nrc.gov.

Sincerely,

/RA/

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

cc: J. Lynch, Region III
L. Malmud, M.D., ACMUI

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