From: Lanzisera, Penny
To: wayne.richardson@bebig.com
Subject: Amendment Request
Date: Thursday, August 07, 2014 1:34:00 PM

Eckert & Ziegler BEBIG, Inc.
License Number 06-30764-02MD
Docket Number 03036179
Mail Control No. 583881

Mr. Richardson,

In order to continue our review or your request to add a new source model/plaque to your license, we need the following additional information:

1. A copy of the USA license allowing possession of the Ru-106 sources. This license has the responsibility of ensuring that the sources that are distributed meet the Sealed Source and Device Registry (SSDR) requirements and is typically a manufacturing license that reviews the overseas manufacturing.

2. The SSDR provided continues to list Isotope Products Laboratories as the distributor. Please submit an amended registration listing Eckert & Ziegler BEBIG, Inc. located in Oxford, CT.

3. As discussed in Appendix U to NUREG-1556, Volume 12, your product labeling must fulfill the requirements of 10 CFR 20.1901, 20.1904, 20.1905 and of 10 CFR 32.74(a)(2)(viii) and 32.74(a)(3). As excerpted from Volume 12: A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate instructions from a radiation safety standpoint for handling and storing the source or device. For example, the instructions may specify the use of extremity monitors, the use of tongs or other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding, and any special procedures needed in the handling and sterilizing of “fragile” sources (e.g., iodine-125 seeds). A label, leaflet, or brochure must also contain the licensing statement required by 10 CFR 32.74(a)(3). For sources, the statement should read, “The (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to [10 CFR 35.57, 35.400, or 35.500] or under equivalent licenses of Agreement States.” For each type of sealed source or device you intend to distribute, please:

    a. Submit copies or facsimiles of the labels that will accompany the product and specify where each label will be placed (e.g., on the device, on the source shield); and
    b. Submit copies of all leaflets and brochures that will accompany the product.

4. Documentation to show that the BeBig Plaques Rum 101 – Rum 114 referenced in the FDA 510k are the same as the plaques referenced in the SSDR provided.

5. It appears that you will allow return shipments of sources and devices. As discussed in Appendix U to NUREG-1556, Volume 12, please provide instructions

provided to customers that include the following:

a. Establishes the user's responsibility and liability as the shipper;
b. Provides step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
c. Discusses all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189. This discussion of the customer's responsibilities should include (but is not limited to):

• The requirements to survey and wipe-test packages;
• The distance at which to survey packages;
• The action levels for the package wipe-test results;
• The dose rate limitations on the particular shipping label that you will provide; and
• The need for sealing tape or another mechanism to fulfill the security seal requirement.

If the manufacturing oversight will be conducted under License Number 06-30764-01, please submit a request to amend this license. In the interim, your request to amend the distribution license will be voided pending receipt and approval of this request. At that time, you may resubmit your request to allow distribution of Ru-106 sources/plaques with inclusion of the information described above. The request may be faxed to 610-337-5269 or sent via signed pdf to my attention. Please refer to Mail Control No. 583881 in your response.

Sincerely,

Penny Lanzisera
US NRC, Region I