

February 21, 2012

Michael A. Welling, Assistant Director
Radioactive Materials
Division of Radiological Health
Department of Health
109 Governor Street, Rm. 730
Richmond, VA 23219

Dear Mr. Welling,

This is a response to your e-mail sent to Ms. Lymari Sepulveda of my staff, dated February 8, 2012, requesting confirmation that the Model HEGL-0124 source can safely be used in the Dilon Technologies, Inc. (Dilon), Model 03-000xx series medical localization device.

We have conducted a safety evaluation of the application that we received from Dilon to register the device in accordance with the provisions of 10 CFR 32. The safety evaluation was conducted in accordance with the applicable guidance in NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration." For the safety evaluation of the device, we also utilized the expertise of the NRC's Medical Team. Our safety evaluation found that the device, including the Model HEGL-0124 source, if used as the Dilon application stated, met the regulatory requirements; and we issued registration certificate No. NR-1343-D-101-S for the device.

If you have further questions, please contact Ms. Lymari Sepulveda of my staff at lymari.sepulveda@nrc.gov, or the telephone at 301 415-5619.

Sincerely,

/RA/ John Jankovich for
Kevin R. O'Sullivan, Branch Chief
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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