August 9, 2001

Good Day, Dr. Seung Lee:

I am responding to your third request for information (e-mail dated August 9, 2001). These responses will also be included in our response to your second request, which I am currently working on.

Clarification of Device (SSD) Labeling I.A.W. 10 CFR 32.25(b):

> *10 CFR 32.25(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified...*
>
> Our intent in this application is to label the LENS CAP, which is the individual part of the SSD containing the GTLSs, with both the radionuclide (^{3}H) and the initial transferor's website address (www.teknolite.com) specific to the SSD model. This website will contain the full information on the SSD, as well as the full contact information of the initial transferor (Litepro, LLC). It was our understanding, based on a recent discussion with the NRC, that this would satisfy the regulatory requirement.
>
> The initial application, Section 4.2 "Labeling," contained errors. It should read as follows:
>
> "Each SSD lens cap (where the GTLSs are encapsulated) will be labeled with the isotope name (^{3}H) and the initial transferor's website address (www.teknolite.com) specific to the SSD model ~~on the flashlight lens cap where the GTLS are encapsulated~~. This website address will contain detailed information about the SSD, including the full contact information of the initial transferor."
>
> NOTE: SSD body labeling requirements should be removed from the application, and all requirements are specified for the lens cap only, since it is the lens cap that contains the GTLSs.
>
> The lens cap has very limited space for labeling. It already has a label showing operating instructions (rotation directions for turning the SSD "ON" and "OFF"). Due to the limited space, the applicant asked the NRC representative if labeling the lens cap with the initial transferor's website address (www.teknolite.com) specific to the SSD model would be adequate. The applicant went on to point out that this website would contain detailed information about the SSD, including the full contact information of the initial transferor who is also the U.S. Distributor, as well as the applicant, Litepro, LLC. The logic was that the initial transferor's website (www.lite-pro.com) was less adequate because, although it would contain detailed contact information, the observer would have to select the link to the actual Teknolite™ website for detailed product information. Furthermore, it was the applicant's

understanding that providing this SSD website address would allow the ...*initial transferor of the product*...to...*be identified*, since providing all initial transferor information on the lens cap is not practical due to space limitations.

The website address (www.teknolite.com) has already been established and will be updated with all applicable SSD and initial transferor information pending issuance of the SSD registration.

As a general note, the SSD body will not contain Litepro, LLC's name for the following reason:

For business reasons, Litepro, LLC has designed the SSD body so that it can be labeled with a vendor's name (this allows secondary distributors other than Litepro, LLC to receive the products labeled with their own names). Therefore, the applicant requests that the SSD body not be held to regulatory labeling requirements, so long as the lens cap meets such requirements. Each secondary distributor, if contacted directly, will also be able to provide full contact information on the initial transferor, Litepro, LLC.

Clarification of Audit Frequency in QC Program, Part J, Section 1.0:

Section 1.3 has been revised as follows:

"1.3 The audit frequency should initially be on a monthly basis; the frequency can be increased at the discretion of the QCM; a decrease in frequency should be approved by the QCD and should be based on the merit of program performance. <u>The maximum duration between routine audits will be quarterly, not to exceed four (4) months."</u>