PROFESSIONAL RADIATION CONSULTING, INC.
4192 Lookout Drive
Loveland, Colorado 80537-3596
Phone: (970) 203-0195
Mobile: (970) 481-5302
Fax: (720) 294-1153
E-mail: ProRadCon@aol.com

August 10, 2001

United States Nuclear Regulatory Commission

ATTENTION: Dr. Seung Lee

Room 8F8, Mail Stop T8F5

Two White Flint North

11545 Rockville Pike, Maryland 20852-2738

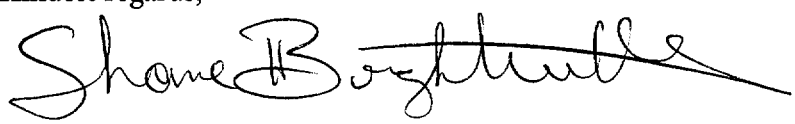
RE: Litepro, LLC Response to Nuclear Regulatory Commission's Second and Third Requests for Additional Information on Sealed Source Device Safety Evaluation Application

Dr. Seung Lee:

The following are responses to your second and third requests for additional information, dated August 01, 2001, and August 09, 2001, respectively, regarding the Litepro, LLC application for Teknolite™ Sealed Source Device Safety Evaluation and Registration. The responses are numbered according to the numbering sequence of the items requested.

If you have any questions or comments, please contact me at (970) 203-0195 or Mr. Joseph Tchira at (305) 931-6990.

Kindest regards,



PROFESSIONAL RADIATION CONSULTING, INCORPORATED

Shane Brightwell, President

CC: Joseph Tchira, Litepro President

RESPONSES TO NRC's SECOND REQUEST FOR ADDITIONAL INFORMATION, DATED AUGUST 01, 2001, REGARDING SEALED SOURCE DEVICE SAFETY EVALUATION APPLICATION

Quality Control Program

1. **Clarification of SSD Manufacturer's Assembly, Inspection, and Testing Personnel Training**

   i) QC Program Part C is revised to add the following as the first bulleted item:

   - This QC Program document and the standard operating procedure for SSD performance testing (Appendix B of the Application) will serve as the training documents for training all manufacturer's assembly, inspection, and testing personnel.

   ii) QC Program, Attachment QC-1: Employee Training/Evaluation, has been revised to include the training topics, topic durations, and the exam pass/fail requirements.

2. **SSD Manufacturer's Receipt and Lot Testing (LTPD) Requirements**

   i) As stated in QC Program Part F, Section 2.0, 100% of all GTLSs will be visually inspected prior to use in SSD manufacturing.

   ii) QC Program Part F, Section 4.0 has been revised to require 100% visual inspection of assembled lens caps for
   - proper assembly;
   - proper marking/labeling, and
   - proper GTLS brightness.

   iii) As stated in QC Program Part G, each assembled lot of SSDs will be subject to lot testing in accordance with 10 CFR 32.110 at an LTPD of 5%. Additionally, as stated in Section 1.4, the testing of the SSD samples will be performed in accordance with

the requirements in ANSI/HPS N43.4-2000 for all seven applicable tests. The applicant believes that it is prudent to test the integrity of the GTLS after its incorporation into the assembly of the SSD and not before.

3. U.S. Distributor Leak Testing

QC Program Part G has been revised to include the requirements for U.S. distributor 5% LTPD lot testing inspections of final packaged SSDs for

- proper lens cap marking/labeling (design conformance), and
- proper GTLS brightness for leakage indication (in lieu of removable contamination measurements).

4., 5. Clarification of QC Testing Procedure and Documentation

i) The QC Program testing procedure (Part G) incorporates the testing procedure in the Application Appendix B (based on ANSI/HPS N43.4-2000) to satisfy the requirements in 10 CFR 32.110. This procedure is performed on the fully assembled SSD. In implementing this procedure, each SSD sample selected from the production lot is subjected to all seven of the applicable tests.

ii) Regarding QC documentation:

- QC Program Attachment QC-2 is intended as the certificate issued by the manufacturer for completion of the 100% assembled lens cap inspection and lot testing procedure (Application Appendix B) as it applies to the requirements of the QC Program.

- Attachment QC-2 is generated <u>in addition to</u> (not in place of) Forms A-1/A-2 of the testing procedure in Application Appendix B.

- Both (a) Forms A-1/A-2 and (b) Attachment QC-2 are required to be generated and maintained on file by the manufacturing facility for each production lot.

- Forms A-1/A-2 are intended for documenting the details of testing results.

- Attachment QC-1 is intended to summarize the results and has been revised to list all three lens cap inspection items as well as all seven of the applicable lot testing requirements and the subsequent testing results (pass/fail).

Typographical Errors

Responses

1. **Exposure Pathway:** Normal Routine Use

The assumption was correct; the revision is below:

EDE_{SSD} = 0.004 mrem/yr * 3.1 * 0.0625 = **0.0008 mrem/yr**

2. **Exposure Pathway:** Normal Handling, Storage, Distribution, and Transport of Multiple Exempt Units

The assumption was correct; the revision is below:

EDE_{SSD} = 0.1 mrem/yr * 3.1 = **0.31 mrem/yr**[(2)]

The following correction was also made to the same section:

[2] This value was entered as **0.32 mrem/yr** in the dose table in Section 5.2.1 of the report.

QC Program

1. **Paul Moreton is the Quality Control Manager.** See accompanying corrected QC Program.

2. **ANSI/HPS N43.4-2000 is the correct reference.** See accompanying corrected QC Program, Attachment QC-2.

RESPONSES TO NRC's THIRD REQUEST FOR ADDITIONAL INFORMATION, DATED AUGUST 09, 2001, REGARDING SEALED SOURCE DEVICE SAFETY EVALUATION APPLICATION

1. 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 (^3H) 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 (^3H) 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.

2. **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; adecrease 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>

Section 2.3 has been revised as follows:

"2.3 The audit frequency should initially be on a semi-annual basis; the frequency can be increased or decreased at the discretion of the QCD andshould be based on the merit of program performance. The maximum duration between routine audits will be annually, not to exceed fourteen (14) months."

TRK# 8293 6430 3074 FORM 0200

14AUG01
AA

20852 -MD-US

IAD
XA GAIA

FedEx Envelope

FedEx USA Airbill Express

8293 6430 3074

0200

FedEx Retrieval Copy

1 From

Date: 8-10-01

Sender's FedEx Account Number:

Sender's Name: Shane Brightwell Phone: 970 481-5302

Company: Professional Radiation Consulting, Inc.

Address: 4192 Lookout Dr.

City: Loveland State: CO ZIP: 80537-3596

2 Your Internal Billing Reference: 000105

3 To

Recipient's Name: Dr. Seung Lee Phone: 301 415-5787

Company: U.S. Nuclear Regulatory Commission

Address: Room 8F8, Mail Stop T8F5

Two White Flint North

11545 Rockville State: MD ZIP: 20852-2738

8293 6430 3074

4a Express Package Service — Packages up to 150 lbs

X 1 FedEx Priority Overnight 5 FedEx Standard Overnight 6 FedEx First Overnight

20 FedEx Express Saver 77 NEW FedEx Extra Hours

4b Express Freight Service — Packages over 150 lbs

7 FedEx 1Day Freight 8 FedEx 2Day Freight 83 FedEx 3Day Freight

5 Packaging

X 6 FedEx Box 2 FedEx Pak 1 Other Pkg

6 Special Handling — Includes FedEx address in Section 3

3 SATURDAY Delivery 2 SUNDAY Delivery 1 HOLD Weekday at FedEx Location 31 HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?
One box must be checked.

No 4 Yes 6 Dry Ice — Cargo Aircraft Only

7 Payment Bill to — Enter FedEx Acct. No. or Credit Card No. below

1 Sender 2 Recipient X 3 Third Party 4 Credit Card 5 Cash/Check

FedEx Acct. No. 2458-3491-8 Exp. Date

Total Packages: 1 Total Weight: < 1 lb Total Charges

8 Release Signature

Shane B.

404

Rev. Date 12/00 • Part #159915 • GBFE 5/01