

## ENCLOSURE

Regarding the issues addressed in Mr. Shane Brightwell's letter, dated July 24, 2001, we need the following information in the Appendix C, "Quality Control Program for Litepro, LLC Model Teknolite Torch Sealed Source Device" to complete our review on your application for registration certificate:

1. On Page 2, the application stated that "Personnel performing assembly and inspections of the SSD will be trained and observed to satisfactorily perform the assembly/inspection procedures; training and observations will be documented accordingly (Attachment QC-1)." However, the application did not provide the content of the required training. Please specify what subjects to be addressed in the training, their durations, and their pass/fail requirements.
2. On Pages 3 and 5, please verify that the manufacturer will perform receipt inspection on the incoming gaseous tritium light sources (GTLS) from the mb-microtec. Please also specify the final SSD inspection before shipping to the US distributor using the sample size specified in the Table on Page 6.
3. On Page 8, please verify that the US distributor perform leak test using the sample size specified in the Table on Page 6 prior to distribution in US markets.
4. On Page 1 of 2 in Attachment QC-2, the Section 2.3 states that random samples of production lots are tested per ANSI/HPS 43.4-2000. This standard requires 7 different tests (i.e., discoloration, thermal shock, pressure, impact, vibration, and immersion); but these tests are to be conducted on the GTLS. Therefore, please clarify how you intend to use these tests for production lots. On Page 2 of 2 in Attachment QC-2, you described drop and leakage tests, each to be passed/failed. Please provide descriptions of two tests and pass/fail criteria for each of the two tests.
5. On Page 2 of 2 in Attachment QC-2, please provide the pass/fail criteria for drop test and leakage.

Typographical errors in Responses:

1. On Page 3, Exposure Pathway: Normal Routine Use, we assume that you intended the  $EDE_{SSD}$  to read 0.0008 mrem/yr, instead of 0.008 mrem/yr.
2. On Page 4, Exposure Pathway: Normal Handling, Storage, Distribution, and Transport of Multiple Exempt Units, we assume that you intended the  $EDE_{SSD}$  to read 0.31 mrem/yr, instead of 3.1 mrem/yr.

Typographical errors in QA program:

1. On Page 1, Paul Moreton is Quality Control Manager, not Quality Assurance Manager.
2. The ANSI/HPS standard should read N43.4-2000, not N43.3-2000, in Sections 1 and 2 on Attachment QC-2.

Joseph Tchira, President  
 Litepro, LLC  
 3731 North Country Club Drive, Suite 525  
 Aventura, FL 33180

SUBJECT: Second REQUEST FOR ADDITIONAL INFORMATION ON TEKNOLITE  
 FLASHLIGHT

Dear Mr. Tchira:

This letter is in response to the issues addressed in Mr. Shane Brightwell's letter, dated July 24, 2001. In order to continue our evaluation, we need additional information in the Appendix C, "Quality Control Program for Litepro, LLC Model Teknolite Torch Sealed Source Device." They are attached in the Enclosure.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

This letter requests information regarding the registration of your product only. You will receive separate communication regarding your application for a distribution license.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

/RA/

Seung J. Lee, Mechanical Engineer  
 Materials Safety and Inspection Branch  
 Division of Industrial and  
 Medical Nuclear Safety  
 Office of Nuclear Material Safety  
 and Safeguards

Enclosure: As stated

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August 1, 2001

Joseph Tchira, President  
Litepro, LLC  
3731 North Country Club Drive, Suite 525  
Aventura, FL 33180

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION ON TEKNOLITE  
FLASHLIGHT

Dear Mr. Tchira:

This letter is in response to the issues addressed in Mr. Shane Brightwell's letter, dated July 24, 2001. In order to continue our evaluation, we need additional information in the Appendix C, "Quality Control Program for Litepro, LLC Model Teknolite Torch Sealed Source Device." They are attached in the Enclosure.

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If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

*/RA/*

Seung J. Lee, Mechanical Engineer  
Materials Safety and Inspection Branch  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: As stated