



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

**APR 26 1994**

MEMORANDUM FOR: Steven Baggett, Chief  
Sealed Source Safety Section  
Source Containment and Devices Branch, IMNS, DRSS

FROM: Ronald R. Bellamy, Chief  
Nuclear Materials Safety Branch  
Division of Radiation Safety and Safeguards, RI

SUBJECT: REQUEST FOR A DEVICE EVALUATION  
CONTROL NO. 116381, LICENSE NO. 06-17253-01,  
VICTOR J. BORTOLOTT, Ph.D.

As you requested, attached are the renewal application and supplementary information regarding the devices currently being used, and proposed for use by the licensee, Victor J. Bortolot, Ph.D., License No. 06-17253-01, Control No. 116381. Work on this renewal has been delayed due to non-payment of fees. Dr. Bortolot submitted payment with his letter dated March 4, 1993 but disputes the fee category and fees assessed based on three major concerns listed below. Although the regional staff is not involved in the assessment of fees, we request assistance in the following areas to properly categorize and authorize the activities of this licensee:

1. He disagrees with the categorization of his device as a "measurement instrument" but states that it should be an "irradiator".

Please confirm which is the correct categorization of this device. As requested, the following documents are enclosed which describe the device through its licensing history:

- \* Cover page of the 1976 application which includes Item 7, describing the purpose of the sources as thermoluminescent sensitivity calibration.
- \* A letter dated December 13, 1976 providing additional information about the sources and devices.
- \* Enclosures from the 1981 renewal application: "Daybreak Nuclear and Medical Systems Inc, Product Description, Thermoluminescence Apparatus for Archeological Dating"; "Thermoluminescent Dosimetry in Medicine and Archeology"; and "Thermoluminescent Authenticity Testing".
- \* The product brochure "Daybreak Systems for TL Research" from the 1986 renewal application.

9501090067

2. He does not understand why a device review is needed because of the change to the 1100 automated TL measurement system. As he states, the TL measurement system does not contain licensed sources. However, his application does request use of a new source in an improved irradiator; the irradiator is attached to the 1100 automated TL measurement system.

Please be specific as to which devices require review, if any. Although the 1100 automated TL measurement system may NOT require review, the improved irradiator may. It is described in the application dated March 20, 1992, Items 8 and 9 including diagrams and description, and is identified as the strontium-90 irradiator II and Daybreak Model 740. A copy of the "Product Description, Model 1100 Automated TL System" is also enclosed with this application. Please note that on Page 2, it states that the Model 1100 is "intended for use with the 801 multiple sample irradiator."

Please determine if any additional irradiators, or devices used with the irradiators, require a device review. Currently, the only device manufactured by Daybreak which has been reviewed is the custom device possessed by the Detroit Institute of Arts; this device is Sample Irradiator Model 801 (referred to as the 801 Multiple Sample Irradiator" in the 1986 product brochure). In addition to this device, the brochure also describes a Model 740 Beta Irradiator, a Model 750 Alpha Irradiator, a Model 760 Vacuum Alpha Irradiator, and a Model 765 Vacuum On-Plate Alpha Irradiator.

3. He states that he does not manufacture devices with sources, however he does manufacture devices which customers may load themselves with sealed sources. Instructions for source loading are stated in the "Daybreak Model 740 Beta Irradiator, Revision 2, 21 November 1984" submitted with the March 20, 1992 renewal application. For this reason, he believes that he is not required to have the device reviewed. He further states that, if a device review is required in order for commercial distribution, his sales volume does not justify the expense of maintaining the device registration and he will withdraw his request for distribution and will make his device drawings publicly available.

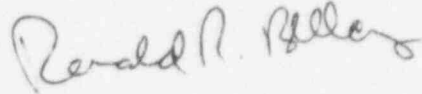
Based on past correspondence, we understand that a device review and registration is needed for distribution of the devices. Please confirm if a device review and registration is needed for possession and use of the sources in devices in his analytical laboratory as he has been licensed in the past.

Memorandum  
Steven Baggett

-3-

If you have any additional questions or need further information, please contact Betsy Ullrich, the technical reviewer for this action, at 610-337-5040.

Sincerely,



Ronald R. Bellamy, Chief  
Nuclear Materials Safety Branch

Enclosures:

1. Letter dated March 4, 1993 to Glenda Jackson, NRC from Victor Bortolot, Ph.D. of Daybreak Nuclear and Medical Systems, with enclosures
2. Letter dated March 20, 1992 requesting renewal, with enclosures
3. "Daybreak Systems for TL Research" brochure from the 1986 renewal
4. Daybreak Nuclear and Medical System, Inc "Product Description - Thermoluminescence Apparatus for Archeological Dating" from the 1981 renewal
5. "Thermoluminescence Dosimetry in Medicine and Archaeology" paper from the 1981 renewal
6. "Thermoluminescence Authenticity Testing" brochure from the 1981 renewal
7. Letter dated December 13, 1976 providing additional device information
8. Page 1 of the application received October 21, 1976