



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 19, 2000

Mr. Patrick A. Hancock, Safety Engineer
Safety and Environment Branch
Goddard Space Flight Center
Greenbelt, MD 2077-001

Dear Mr. Hancock:

This letter is in response to your request dated April 3, 2000, requesting a custom registration of Model 672 J. L. Shepherd Irradiator. In reviewing the application, we find that it is lacking significant amounts of the required information. Specifically, your application did not provide the following information related to the Irradiator Model 672:

- finalized complete approved design and technical drawings,
- description of source models, specific and maximum activity of the sources,
- finalized specific installation, operational and maintenance manuals or procedures,
- updated Quality Assurance Manual for the design and fabrication of the model,
- declaration for withholding of proprietary information through a notarized affidavit as specified in 10 CFR 2.790.

Please note that references and inferences to other irradiator models are not sufficient for us to conduct a safety evaluation and issue a registration certificate for the Model 672. The design and historical performance data provided for any existing irradiator must lend support to your application and assist in the establishment of the fact that the new customized model has similar or enhanced safety features to outweigh the need for a prototype test on the Model 672. In the Enclosure to this letter we have delineated further specific issues which you must also address when resubmitting your application for approval.

With incomplete documents and unavailability of adequate information the NRC Staff is unable to complete a safety evaluation of your device. Therefore, we have discontinued the review of your application. This is without prejudice to re-submission of your application. If you decided to re-submit your application for registration, please ensure that you have included sufficient information to allow NRC to evaluate your device.

If you have any questions, please call me on (301) 415-7273 or Ujagar S. Bhachu of my staff on (301) 415-7894.

Sincerely,

Frederick Sturz, Section Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: Additional Information Needed For Safety Evaluation.

Patrick A. Hancock, Safety Engineer
Safety and Environment Branch
Goddard Space Flight Center
Greenbelt, MD 20771

June 19, 2000

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/RA/
Frederick Sturz, Section Chief
Materials Safety and Inspection Branch
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Office of Nuclear Material Safety
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Enclosure: Additional Information Needed For Safety Evaluation.

cc w/encl: SKimberley, LFDCB

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