

NASA-Goddard Space Flight Center

Enclosure

Additional Information Needed For Safety Evaluation

We have completed a preliminary review of your application dated April 3, 2000, for the J. L. Shepherd, Model 672 Custom Beam Irradiator. The review indicated that the following issues have not been adequately addressed in your application.

1.0 Source

- 1.1 SSD registration certificate CA-598-S-112-S indicates maximum activity of a Cobalt-60 source capsule as 16,000 Ci. J. L. Shepherd drawing No. A-0672-7810, under item 6, indicates a maximum activity of source capsule as 20,000 Ci. Please address this apparent discrepancy.
- 1.2 Page C-2 of the check list indicates a total combined Cobalt-60 source activity for three sources as 48,000 Ci. However, the J. L. Shepherd Drawing No. A-0672-4 indicates a combined activity of 44,000 Ci. The Model 7810 source classification in the check list is C-43434, page A-1-2 indicates it as E-43434 and the registration certificate shows the classification as ANSI 77E-43424. Please have these apparent discrepancies resolved.
- 1.3 Please provide the isodose curves for open and closed positions of the sliding shutter for the single source and combined maximum activity initially and at 5 cm, 30 cm and 100 cm. Please clearly mark the dose rates and provide explanations for significant variances in the contours of radiation isodose curves. Please provide the basis of your estimation and any assumptions made (i.e source assembly considered as a line source or a point source). Please include backscatter in your estimations. If credit is taken for external shielding or barriers that restrict access to higher radiation areas, the radiation levels at the barrier and at a 12" distance from it need to be included with the application (see Section 10.6 NUREG 1556 Vol. 3)
- 1.4 Please provide the names of the suppliers of sources to be used in the Model 672, the specific activity and the centerline temperature of the sources during transportation storage and normal operations. What is the maximum movement and rate of movement of the sources during normal and abnormal operations?

2.0 Prototype Testing

- 2.1 Since you are requesting a single custom irradiator registration for use by NASA, prototype testing may not be necessary. However, you must adequately demonstrate that the Model 672 irradiator during normal and accident conditions will maintain its integrity.
- 2.2 In your application you have relied upon comparison and historical performance of existing products to demonstrate that the ability of your unit to operate safely and to maintain its integrity is equivalent to or more robust than the previously-approved units. However, you have not supplied adequate information in support of your intended claim by delineating similarities and differences between the irradiators.

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2.3 Your application portrays that Model 672 is “identical” to the Model 81, hence, relies on the performance of the Model 81 irradiators. Please note that there are several sub-types of the Model 81 and it is not clear which model the Model 672 is being compared to. On one drawing Model 81-26 is referenced and that model cannot be found on any certificate registered with the NRC. In another instance, a drawing has a parenthetical reference to BNL Model-1. Also, all Model 81's can hold up to four sources of any three different isotopes (Cobalt-60, Cesium-137, and Europium-152), while the Model 672 is restricted to Cobalt-60. Please clarify how you justify the use of the performance of Mark 1 irradiators to support the integrity of the design and operational requirements of the Model 672.

3.0 Quality Control and Quality Assurance

Please submit a current copy of the Quality Assurance Manual which applies to the Model 672 irradiator.

4.0 Operating and Emergency Procedures

No operating manual was submitted with the application. An operating manual is required for the safety evaluation as specified in Section 8.10.6 of NUREG 1556 Vol. 5. The manual is especially important in the case of your application since a worker may be allowed to be present in the room with the irradiator shutter open and the sources are in the extended position (cleaning and maintenance of source rod system and installation of sources).

5.0 Maintenance Manual

Please provide information on the maintenance requirements as outlined in Section 10.8, NUREG 1556 Vol. 3.

Please note that the licensee must routinely maintain self-shielded irradiators according to the manufacturers (or distributors) written recommendations and instructions. Radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and sources integrity are not compromised. Please confirm that non-routine maintenance shall be performed by the self-shielded irradiator manufacturer or a person specifically authorized by NRC or an Agreement State.

6.0 Installation

The installation procedure provided does not discuss the inspection of the Model 672 for damage during shipment, check/test of all the safety interlocks after installation, access control, check/test emergency lights, etc. Please provide details of such activities.

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7.0 Please Provide Additional Information Regarding:

- training program details for individuals working with the irradiator,
- the expected dose of all workers with the irradiator,
- procedures regarding emergencies, leak tests, and source loading and unloading,
- procedures for onsite storage and disposal of sources.

8.0 A Request for Withholding of Proprietary Information

Pursuant to your request we reviewed your application and material in accordance with the requirements of 10 CFR 2.790. We are unable to grant your request for withholding of information as stated in your application. In general, only that information which cannot be obtained through observations or measurements of components or documentation obtainable by a member of the public can be withheld as proprietary material.

With regards to engineering drawings, information generally considered being proprietary includes information such as dimensional tolerances, technical specifications of materials, manufacturing notes or specific assembly directions. Please identify specific information on each drawing that you wish to withhold as proprietary per 10 CFR 2.790 (b) (1) (ii) and provide nonproprietary versions in accordance with 10CFR 2.790(b)(1)(ii).

An affidavit attested by a Notary Public must be submitted prior to the staff making its final determination. The affidavit and documents to be withheld must be submitted to the NRC in 30 days from the date of this letter. If not in accordance with 10 CFR 2.790 (c), the information sought to be withheld will be placed in the NRC Public Document Room.

