

JUL 24 1986

License No. 29-02786-03
Docket No. 030-06990
Control No. 103680

Ethicon, Inc.
ATTN: Mike Cascio
Radiation Safety Officer
Route 22
Sommerville, New Jersey 08876

Gentlemen:

This is in reference to your application dated June 25, 1986 to renew License No. 29-02786-03. In order to continue our review, we need the following additional information:

1. In Item 6. of your application, you indicate that certain products which you intend to irradiate contain small quantities of isopropanol. Please provide information regarding the precise quantity of isopropanol which is likely to be in the irradiator cell at any one time, the manner in which it is packaged and measures that you will take to ensure that temperatures do not exceed the flash point of the isopropanol.
2. In Item 8. of your application you describe the training individuals will receive prior to being authorized as an operator. You indicate that individuals named in Item 7. will provide this training. From the information you submitted regarding these individuals' training, it appears that none of them have the requisite experience in the actual use and operation of the irradiator. Please submit additional information regarding these individuals' experience in the use and operation of the irradiator. This experience should include at least three months of experience in irradiator operation with at least one month of "hands on" operation of the irradiator.
3. In Item 9, of your application, you indicate that a second float switch will shutdown the irradiator when it is activated by the pool water level dropping more than six (6) inches below the make-up water switch. In addition, Section 20.203(c)(6)(iii) of 10 CFR Part 20 requires that visible and audible alarms be generated upon failure or loss of the liquid shield. Please confirm that such alarms are generated when the pool water level drops eight inches below normal.
4. Section 20.203 (c)(6)(viii) of 10 CFR Part 20 requires that entry and exit portals, which are used in transporting material to and from the irradiation area, be controlled by devices and administrative procedures as necessary to protect and warn against inadvertent entry by an individual through such portals. Please describe how you will comply with the above regulation.

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5. Section 20.203(c)(6)(vii) of 10 CFR Part 20 requires that entry control devices required by 10 CFR 20.203 (c)(6)(i) be tested each day prior to initial operation of the irradiator that day, unless it has been in operation continuously from the previous day, or before resuming operations after an unintended interruption. Please describe the tests which will be performed to comply with this section and include the manner in which the results of these tests will be recorded.
6. Please describe the testing program which you employ to ensure that all safety systems are operating properly. The description should include which tests will be performed, how and by whom the tests will be performed, and with what frequency they will be performed.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 103680.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original Signed By:

John E. Glenn

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

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