License No. 29-03405-02 Docket No. 030-05291 Control No. 122836

Peter J. Branch Executive Vice President Branch Radiographic Labs, Inc. 32 South Avenue West Cranford, New Jersey 07016

Dear Mr. Branch:

This is in reference to your letter dated May 22, 1995 requesting an exemption from the performance requirements in 10 CFR 34.20 for your Amersham Model 520 exposure device. In order to continue our review, we need the following additional information:

1. Please provide your special or unique reason(s) to warrant an exemption for the use of the Amersham Model 520 exposure device instead of an exposure device that meets the current requirements of 10 CFR 34.20. Your response should clearly indicate that your need for the Model 520 cannot be met by an exposure device that already meets current requirements of 10 CFR 34.20.

If you can demonstrate that the use of the Amersham Model 520 exposure device is for an unique or limited special case, then you must specifically request an exemption from 10 CFR 34.20(a) for the device since the Model 520 exposure device was not prototype tested in accordance with American National Standards Institute N432-1980 (ANSI-N432).

- 2. Based on our review of registration sheets, the Amersham Models A453-2 and A453-5 sealed sources may be used in the Amersham Model 520 exposure device; however, the Model A453-5 currently installed in your exposure device may not meet 10 CFR 34.20 criteria for source assemblies. In order to demonstrate that the Model A453-5 sealed source meets 10 CFR 34.20 requirements, please provide the information in Section 7 of ANSI-N432.
- 3. 10 CFR 34.20(c)(4) requires that sealed sources be engraved or have a label attached with the words "DANGER-RADIOACTIVE". The manufacturer has indicated that if the source was manufactured before 1991, it is unlikely that the source was labeled in accordance with 10 CFR 34.20(c)(4). Please determine if the sealed source in your Model 520 exposure device was labeled in accordance with 10 CFR 34.20(c)(4). If the source was not labeled in accordance with 10 CFR 34.20(c)(4), you will need to request an exemption from this provision of NRC regulations.

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As indicated in Information Notice 95-58, other engineering features, use limitations and/or procedures that would reasonably and adequately compensate for not complying with the safety provisions of 10 CFR 34.20 must be considered when evaluating exemptions from equipment requirements. The engineered safety features described in your Model 657 control system for the Model 520 exposure device include an electric motor to activate the drive cable, which in turn, drives the source into an exposed position. If the power to the motor is lost, then a manual crank arrangement must be then used to return the source to the safe shielded position. The NRC is concerned that the manual crank arrangement does not reasonably and adequately compensate for not complying with the safety provisions of the regulations. Please confirm that an engineered safety feature that will automatically return the source to its safe shielded position if electrical power to the motor is lost will be incorporated into the Model 657 control system or Model 520 exposure device. Your response should include a description and diagram of the safety feature added to the control system or exposure device.

We will continue our review upon receipt of this information. Please reply in <u>duplicate</u> to my attention at the Region I Office and refer to Mail Control No. 122836. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5042.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By: Duncan White

Duncan White Nuclear Materials Safety Branch 3 Division of Nuclear Materials Safety

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Enclosures:

1. 10 CFR Part 34

2. Information Notice No. 95-58

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