

19 JAN 1989

License No. 20-02215-01
Docket No. 030-01845
Control No. 108595

Boston University Medical Center
ATTN: Richard H. Egdahl, M.D., Ph.D.
Director
720 Harrison Avenue
Boston, Massachusetts 02118-2393

Gentlemen:

This is in reference to your application dated March 11, 1988, to renew License No. 20-02215-01. In order to continue our review, we need the following additional information:

1. Item 8.1 of your application states that "in some cases individuals may begin working with radioisotopes that do not have external exposure potential prior to attending the indoctrination class if the RPO apprises their radiation safety training experience and is satisfied that required institution regulations will be disseminated to the individual." Please confirm that the information to be given to the individual prior to working with radioisotopes includes all the required instructions as specified in 10 CFR 19.12 (enclosed).
2. Item 9.2 (7.a.) of your application states that meters with selectable linear scales must be calibrated at no less than one point on each scale. The points should be at least approximately 1/3 and 2/3 of full scale. 10 CFR 35.51 (enclosed) requires that each licensee calibrate two separate readings on each scale that must be calibrated. Please confirm that your calibration procedure will meet the requirements of 10 CFR 35.51.

3. With regard to the calibration of survey instruments, please provide the following:

10 CFR 35.51 requires, that at the time of survey meter calibration, the apparent exposure rate from a built-in or owner-supplied check source be determined and conspicuously noted on the instrument and that each survey instrument be checked with the dedicated check source each day of use.

Please confirm that your procedures will include these requirements for those instruments used in accordance with 10 CFR Part 35 requirements.

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4. Item 7 on page 4 of your Radiation Protection Program Manual states that the Radiation Protection Officer (RPO) is to provide laboratory inspections, radiation surveys, and area monitoring to ensure compliance with all regulations. Please identify the frequency at which laboratories will be inspected by the RPO and confirm whether these inspections will include an audit of the authorized users as well.
5. Item K on page 16 of your Radiation Protection Program Manual states that individual users must maintain an inventory of their radionuclide possession. A periodic surveillance of these records by the Radiation Protection Office will be made in order to assure compliance. Please identify the frequency at which the Radiation Protection Office will review these records.
6. Your current NRC license authorizes the possession of cesium-137 in the form of sealed sources for use in an AECL Gammacell 40 irradiator. Due to recent changes in medical licensing format it has become our policy not to issue a medical license with authorization for an irradiator. Therefore, the irradiator will now require a separate NRC license. Please submit a separate request for a new NRC license along with specific information concerning this device and any procedures concerning its operation, training and safety procedures for our review. Please see the enclosed guide for information you may find helpful.

When submitting this required information, please refer to Mail Control No. 108595.

7. In order for the NRC to determine the adequacy of your Radioisotope Committee's approval procedures for authorized users, please describe thoroughly the mechanisms used by the committee to approve, periodically review and evaluate any special conditions or requirements for proposed and currently authorized users.

Please describe the procedures followed for approving users and describe the records maintained by the Radioisotope Committee. These records are to include but not be limited to specific possession limits; chemical and/or physical form of material authorized; approved use of materials authorized; and any prohibitions or special conditions and or requirements placed on its use.

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. 108595.

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, Ph.D.

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

Enclosure: 10 CFR Parts 19 and 35

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