

License No. 20-19761-02
Docket No. 030-20020
Control No. 110614

Dana-Farber Cancer Institute
ATTN: Steven J. Alford, M.S.
44 Binney Street
Boston, Massachusetts 02115

Dear Mr. Alford:

This is in reference to your application dated April 29, 1989 to renew License No. 20-19761-02. In order to continue our review, we need the following additional information:

1. Please note that Mercury 195 and Gold 195m are not reactor produced isotopes and we therefore do not regulate their use.
2. Please confirm that physicians authorized by the Radiation Safety Committee for human use will meet the appropriate training and experience criteria in 10 CFR 35, Subpart J.
3. Attachment 8.2 of your application indicates that training of nursing staff and ancillary staff will be performed on a frequency determined by the RSO. Please confirm that as a minimum there will be annual refresher training.
4. Your procedures for calibrating your dose calibrators do not indicate what actions will be taken if constancy, accuracy or linearity are not found to be within $\pm 5\%$. Please indicate what actions you will take.
5. Your proposed limits for molybdenum breakthrough on technetium generators should be revised to assure compliance with 10 CFR 35. 204. Your action limit should be 0.07 microcurie of Mo-99 per millicurie of Tc-99m. See Appendix M of Regulatory Guide 10.8, Rev. 2.
6. Your application includes a provision for contaminated lab coats to be sent to the laundry if the contamination is less than 200 dpm using a thin end window G-M. If you desire to launder lab coats with identified contamination present on them, then please describe your procedures for monitoring the effluent concentrations of byproduct materials to assure that you do not exceed the limits in 10 CFR 20.106.

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7. We note that several administrative aspects of your described Radiation Safety Committee (RSC) may not conform to the administrative requirements of 10 CFR 35.22. Please confirm that your committee will conform to these requirements. Please also indicate your present Chairman and his or her experience and training which qualifies them for the position.
8. You have requested that we approve your definition of an unrestricted area as an area where no individual is likely to receive a dose exceeding 500 millirem in a calendar year if an allowance is made for expected occupancy. NRC would expect you to justify such a limit. Your request must be specific and include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. Please also describe what measures you have taken to reduce radiation levels to below those indicated in 10 CFR 20.105(b) and why they are unsuccessful.
9. Your described laboratory survey program may not meet all the requirements of 10 CFR 35.70 which requires daily and weekly surveys and records. Please review Appendix N of the enclosed Regulatory Guide 10.8, Revision 2 and submit equivalent procedures.
10. Since the renewal application was submitted to NRC over three years ago, please update and revise, if necessary, the composition of the Radiation Safety Organization and the Radiation Safety Committee. Also, review and revise, if necessary, 6, 7, and 8 of your NRC license to reflect your current radioactive materials program.

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. 110614.

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,

Thomas K. Thompson,
Senior Health Physicist
Medical Licensing Section D
Division of Radiation Safety
and Safeguards

Enclosures: Regulatory Guide 10.8, Revision 2

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License No. 20-19761-02
Docket No. 030-20020
Control No. 115278

Dana-Farber Cancer Institute
ATTN: Elizabeth R. Gross
Director
44 Binney Street
Boston, Massachusetts 02115

Dear Ms. Gross:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Jenny Johansen

Jenny M. Johansen, Chief
Medical Licensing Section D
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 04
2. Requirements for Materials Licensees
3. NRC Forms 3 and 313

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Dana-Farber Cancer Institute
ATTN: Steven J. Alford
Radiation Safety Officer
44 Binney Street
Boston, MA 02115

Gentlemen:

We are returning Check No. 190875 (\$70) dated July 25, 1991, which accompanied your request for an amendment to Materials License 20-19761-02. We retained Check No. 189038 (\$290) dated June 27, 1991, for the amendment fee specified in fee category 7B of \$170.31, 10 CFR 170 in effect at that time.

We direct your attention to the enclosed Federal Register notice dated July 10, 1991, regarding revisions to the Commission's fee regulations (10 CFR 170 and 10 CFR 171) which became effective August 9, 1991. Applications for licensing actions postmarked on or after the effective date are subject to the revised fees in 10 CFR 170. Additionally, material licensees are subject to the newly established materials license annual fees in 10 CFR 171.

Sincerely,

Signed by
Sandra Kimberley

Sandra Kimberley
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

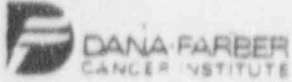
Enclosure:
Check No. 190785 (\$70)

DISTRIBUTION:
License Fee File
OC/DAF R/F
OC/LFDCB R/F (2)
OC/DAF R/F
WP/DANA-FARBER

OFFICE: OC/LFDCB *Rej*
SURNAME: REJacques:ab
DATE: 9/24/91

:OC/LFDCB *SK*
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My
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44 Binney Street, Boston, MA 02115

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VENDOR NO CHECK NO

PAY TO
THE
ORDER
OF

US NUCLEAR REG COMMISSION
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AMOUNT PAID

*****70.00

DOLLARS CENTS

*****70DOLLARS .00CENTS

VOID IF NOT CASHED WITHIN 100 DAYS

BANK OF BOSTON
THE FIRST NATIONAL BANK OF BOSTON
BOSTON, MASSACHUSETTS 02115

AUTHORIZED SIGNATURE

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