MS #16

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030-20020

DANA-FARBER
CANCER INSTITUTE

44 Binney Street, Boston, MA 02115

THE JIMMY FUND

December 3, 1991

Mail Control No. 110614

Thomas K. Thompson
Senior Health Physicist
U.S. Nuclear Regulatory Commission
Medical Licensing Section D
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Thompson:

The following are the responses to your letter dated November 8, 1991, regarding the renewal of License No. 20-19761-02.

1. We note that Mercury 195 and Gold 195m are not regulated.

2. Section 4.2 of the Institute's Radiation Safety Manual will be changed to state 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. Nursing staff and ancillary staff will receive annual refresher training.

4. If the dose calibrator linearity, constancy, accuracy, or channel checks are not found to be within ± 5%, the following actions will be taken:

   a. The medical physicist will be contacted immediately, and the test will be repeated under his guidance.

   b. If the problem persists, the machine will be immediately taken out of service and sent for repairs. For the interim, a spare calibrator will be obtained and calibrated before use.

5. We do not have a Tc-99m generator.

6. We will not plan to launder lab coats that are contaminated. Section 6.3 of the Radiation Safety Manual will be changed to reflect this.

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7. We will conform to 10 CFR 35.22 with regards to the Radiation Safety Committee membership, and the Radiation Safety Manual will be changed to reflect this.

   The Chairperson of the Radiation Safety Committee is Dr. S.T. Treves, and he is certified by the American Board of Nuclear Medicine Physicians.

8. We withdraw our request that you approve our definition of an unrestricted area. Section 6.1.1(b) will be deleted from the Radiation Safety Manual.

9. In areas where radiopharmaceuticals are used, surveys will be conducted in accordance with the model procedure in Appendix N of Regulatory Guide 10.8, Revision 2.

10. The current membership of the Radiation Safety Committee is included as Attachment 1.

    With regard to the request to update section 6, 7, and 8 of the application, if necessary:

    The Radiation Safety Officer is Steven J. Alford, as listed on the current License No. 20-1976-02. See letter dated July 18, 1990.

    Section 7.1 of the Radiation Safety Manual will be changed as in response to #2 above.

    Section 8 of the Radiation Safety Manual will be changed as in response to #3 above.

11. The methods for performing thyroid bioassays for Iodine 125 and Iodine 131 are included as Attachment 2.

It is expected that the above responses satisfactorily meet your requests. Thank you for your attention to this matter.

Sincerely,

Steven J. Alford

Steven J. Alford
Radiation Safety Officer

In duplicate
Attachments
cc: S.T. Treves, M.D.
W. Corbett
L. Gross

Attachment 1
Radiation Safety Committee Members

CHAIRMAN

S.T. Treves, M.D.[1]	CH Nuclear Medicine

MEMBERS

Steven J. Alford	DFCI Radiation Safety
Ronald Amoling	CH Radiation Safety
William Corbett	DFCI Research Administration
John Crigler, M.D.	CH Endocrinology
Karen Flannery, CIH	CH Safety
Jean Gilfillan	CH Endocrine Laboratory
Liz Gross, CIH	DFCI Safety
Robert Johnson	Harvard Radiation Safety
Alun Jones, Ph.D.	Nuclear Medicine Research
Michael Kaplan, D.V.M., D.S.C.	CH Animal Research
William Kaplan, M.D.	DFCI Nuclear Medicine
William New	CH Research Administration
Craig Lillehei, M.D.	CH Surgery
William Lorenzen	Harvard Radiation Safety
Karen Marcus, M.D.	DFCI Radiation Therapy
Alice Rose	DFCI Nursing Education
Frank Osborne	Harvard Radiation Safety
Cheryl Panzarilla, R.N.	CH Nursing
Jacob Shapiro, Ph.D.	Harvard Radiation Safety
Andrew Sonis, D.M.D.	CH Dental
Keith Strauss	CH Radiology
Robert Zimmerman	BWH Radiology

[1] Dr. Treves is also appointed to DFCI Nuclear Medicine

CH = Children's Hospital
DFCI = Dana-Farber Cancer Institute
BWH = Brigham and Women's Hospital

Attachment 2
Thyroid Bioassay Methods

The instrument used for performing thyroid bioassays for Iodine 125 and Iodine 131 is currently a thin crystal NaI detector attached to a scaler ratemeter, and has been calibrated with a contact measurement using an ANSI specified thyroid neck phantom and known activities of the radionuclides mentioned above. The system will be calibrated and used as a scanning device to detect the presence of activity in the thyroid and not as a quantitative technique. The isotopes in question all emit photons in the 27 KeV range which makes identification of individual nuclides virtually impossible using the detector described above. The efficiencies supplied by the calibration offer an estimate of the quantity of activity present in the thyroid gland if only one nuclide is present. If a significant amount of activity is measured, further analysis of the individual will be conducted at Harvard University using procedures already approved in their NRC License.

Individuals conducting thyroid measurements will be trained in use of the instrumentation prior to using radioactive materials, and results of bioassays will be reviewed by the Radiation Safety Officer

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

Dana-Farber Cancer Institute
ATTN: Ronald K. Amoling, II
44 Binney Street
Boston, Massachusetts 02115

Dear Mr. Amoling:

Please find enclosed the renewal of 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."

Mecury 195 and Gold 195m, which is naturally occurring or produced in an accelerator is not byproduct material as defined in Section 30.4(d) of Title 10, Code of Federal Regulations, Part 30 and is not subject to licensing by the NRC. Therefore, you may procure and use it without amendment to your byproduct material license.

You should contact your State regulatory authorities to determine the State licensing or registration requirements for use of this product.

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 NR 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:
Thomas K. Thompson

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

Enclosures:
1. Amendment No. 05
2. Requirements for Materials Licensees