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June 12, 1987

Ms. Jenny M. Johansen, M.S.
Nuclear Materials Safety Section B
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
631 Park Avenue
King of Prussia, PA 19406

Re: License No. 20-17131-01
Docket No. 030-12239
Control No. 106849 Completed

Dear Ms. Johansen,

- 1. By this letter I wish to confirm that we have modified our proposed Radiation Safety Manual to correct in full all the deficiencies enumerated in your letter of 13 May, 1987, with the following exceptions or clarifying comments:
 - (a) (your letter 4.b, page 2) We did not establish a trigger level more restrictive than 200 dpm (35.315(a)(7)) for radiopharmaceutical (Iodine-131) therapy. Cleanup after such therapy is directed by the Radiation Safety Office and the room is not returned to any use until the requirements of 35.315 (a)(7) are met. Thus, unlike other areas where radiopharmaceuticals are used or administered, no later occupant of the room could be exposed to radioactivity in excess of 200 DPM.
 - (b) (your letter 7.b, page 3) We modified our section 8.5.22 to prohibit any visitors under age 18 in therapy rooms unless authorized explicitly on a case basis by the Radiation Protection Officer with specific written instructions.

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(c) (your letter 7.c page 3 and 7.j, page 4) We confirm that a copy of the brachytherapy room survey required by 35.415(a)(4) is given to the BWH Radiation Protection Officer for retention. We do wish to retain our authorization under 20.105(a) for maximum radiation levels in unrestricted areas as follows: (amendment 10 of 6 July, 1986, page 5)

3 millirem in any one hour

125 millirem in any one week

500 millirem in any one year,

measured up to 18 inches from walls in hallways and patient rooms adjacent to rooms occupied by patients undergoing radioiodine therapy or brachytherapy.

- (d) (your letter 7.d, page 3) The title of our manual section 8.6 has been modified to include "iodine and other sealed therapy sources", the intent being to be general rather than specific.
- (e) (your letter 7.i, page 4) The procedures in section 8.8 now explicitly include a requirement that each patient at discharge be given verbal and written instructions to minimize exposures to family and public.
- (f) (your letter 7.k, page 4) The procedures in section 8.5 and 8.6 have been expanded to conform to 35.404, 35.406 and 35.415 (a)(5).

A current membership list for the Radiation Safety Committee is attached.

Certain records pertinent to brachytherapy and to laboratory management are kept on file in the Radiation Safety Office of the Joint Center for Radiation Therapy and of Harvard University, respectively.

We request you delete the requirement for twice annual audits of <u>all</u> permit holders to once annually; we will continue quarterly audits of the major users as previously specified. (Modifies our letter of June 16, 1983, item 12.)

All package receipt wipe test receipts are sent to and kept by the Radiation Safety Office.

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We wish to omit personal air sampling for individual iodination unless there is some indication of procedural deficiency leading to a measurable thyroid uptake. (Modifies our letter of June 16, 1983, item 17.)

We wish to request an explicit exemption from 35.60(b), syringe shields and labels. Our nuclear medicine dose administrations are drawn from multidose vials prepared by our radiopharmacy into shielded syringes, then measured in a dose calibrator prior to each individual injection. To require that a unique label be prepared for each syringe/shield would add both unproductive, time consuming extra work and engender small additional radiation exposures of no benefit to anyone.

Please call immediately if further information is needed to continue your review of our program.

Sincerely yours,

David E. Drum, M.D.

Radiation Protection Officer

DED: JBM



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RADIATION SAFETY COMMITTEE RADIDACTIVE DRUG RESEARCH COMMITTEE

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Edmund B. Cabot, M.D. Philip D. Cobb, M.P.H. David E. Drum, M.D., Chairman Mary Lou Falk, R.N. B. Leonard Holman, M.D. Anthony Howes, M.D. Robert U. Johnson, M.S. Alun Jones, Ph.D. Philip F. Judy, Ph.D. Donald F. Kelly, M.B.A. Linda Laroche Joel M. Rappeport, M.D. Carolyn Rayment, D. Pharm. Jacob Shapiro, Ph.D. Sandor Szabo, M.D. Barbara Weissman, M.D. Gordon H. Williams, M.D.

Specialty

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RADIATION EMERGENCY COORDINATING COMMITTEE

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