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Docket Nos. 030-12239
030-15070
030-22102

License Nos. 20-17131-01
20-17131-03
20-17131-04

Brigham and Women's Hospital
ATTN: Mr. Henry Beltramini
Associate Vice President
Administrative Services
75 Francis Street
Boston, Massachusetts 02115

Gentlemen:

Subject: Inspection No. 85-01

This refers to the routine, safety inspection conducted by Ms. Jenny M. Johansen of this office on August 20 and 21, 1985, of activities authorized by NRC License Nos. 20-17131-01, 20-17131-03, and 20-17131-04 and to the discussions of our findings held by Ms. Johansen with Mr. Kristians Veinbergs and members of your staff at the conclusion of the inspection.

Areas examined during this inspection are described in the NRC Region I Inspection Report which is enclosed with this letter. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Our inspector also verified the steps you have taken to correct the violations brought to your attention in the enclosure to our letters dated April 27, 1982, and November 8, 1983. We have no further questions regarding the steps you took to correct items A., B.1., B.2., and C. in our letter dated April 27, 1982, and items I.A., I.B., I.C., II.A.1., II.A.2., II.B., III.A.1, and III.A.2., in our letter dated November 8, 1983. With regard to items III.A.3. and III.B. in our letter dated November 8, 1983, these items were not fully corrected.

In addition, our inspector examined those activities conducted under your license relating to the subject covered in your letters to U.S.N.R.C. Region I dated March 15, 1983, and August 12, 1983. We have no further questions regarding this matter.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These violations have been categorized by severity level in accordance with the revised NRC Enforcement Policy (10 CFR 2, Appendix C) published in the Federal Register Notice (49 FR 8583) dated March 8, 1984. You are required to respond to this

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letter and in preparing your response, you should follow the instructions in Appendix A. In addition to the need for corrective action regarding these specific violations, we are concerned about the implementation of your management control systems that permitted them to occur. Consequently, in your reply, you should describe in particular, those actions taken or planned to improve the effectiveness of your management control systems.

Another activity appears to be deviation from the corrective actions stated for Item II.A.3. in your letter dated November 30, 1983, as a result of our inspection conducted August 16-17, 1983. Specifically, on August 20, 1985, seals bearing individual code numbers were not placed onto all packages shipped from the Radiopharmacy by the common carrier. Please include, in your response, your comments concerning this deviation.

Item A described in the attached Notice of Violation, involving control of licensed material, is classified as a Severity Level IV violation. As indicated in Supplement IV of the NRC Enforcement Policy, significant violations of this type are normally classified as Severity Level III. However, after careful consideration of the factors involved in this specific instance, we have exercised our judgement under NRC Enforcement Policy and have classified this violation as Severity Level IV. Similar violations of this type in the future may result in additional enforcement action.

Items B. and D.1.b. in the Notice of Violation enclosed with this letter were identified during a previous inspection of your licensed activities on August 16-17, 1983, and were documented in the enclosure to our letter dated November 8, 1983. Your letter to this office dated November 30, 1983, stated that calibration procedures for the dose calibrator now adhere to Regulatory Guide 10.8., Appendix D, and individuals would be tested as part of the quarterly audit to assure that they were aware that the scaling multiplication factor must be used for the molybdenum-99 value on the LED display. From our August 20 and 21, 1985, inspection it appears that the stated corrective actions were not effective since these items have not been fully corrected.

Recurrent and uncorrected violations are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

During the discussion of our findings at the conclusion of the inspection, Ms. Johansen expressed our concern about the dose to the finger tips of the left hand of the Radiopharmacist and Nuclear Medicine technologist who were observed using their index finger and thumb to hold vials containing ≈ 3 millicuries of thallium-201 (radiopharmacist) and ≈ 60 millicuries of technetium-99m MDP (technologist) inside a lead vial shield which did not restrict the vial in the shield while drawing up doses. Additionally, Ms. Johansen discussed the need to fully identify the users of the J. L. Shepherd irradiator under License No. 20-17131-03. Further, Ms. Johansen

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discussed generation of a record to verify that patients discharged from the hospital after iodine-131 treatment for thyroid carcinoma contain residual activity of 30 millicuries or less. From these discussions, we understand that (1) lead vial shields with "screw-on" shield tops will be immediately provided in the Radiopharmacy and Nuclear Medicine in order to reduce exposure to the fingertips while drawing doses; (2) the logbook for the J. L. Shepherd irradiator will list the users last name or a key will be added to identify the initials used to the full name of the user; and (3) the iodine-131 therapy patient's survey record or the patient's medical record will contain a statement that the patient's residual activity was 30 millicuries or less upon release from the hospital. Please confirm our understandings in your reply to this letter.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosures to this letter, and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
James H. Joyner

Thomas T. Martin, Director
Division of Radiation Safety
and Safeguards

Enclosures:
1. Appendix A, Notice of Violation
2. Combined NRC Region I Inspection Report Nos. 030-12239/85-01, 03-15070/85-01, and 030-22102/85-01

cc w/enclosures:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

bcc w/enclosures:
Region I Docket Room (w/concurrences)
Senior Operations Officer
Dan Holody, RI

RI:DRSS	RI:DRSS	RI:DRSS	RI:DRSS
Johansen/djh	Glenn	Joyner	for Martin
10/28/85	10/28/85	10/29/85	10/29/85

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