



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

OCT 25 1988

Docket Nos. 030-12239
030-15070
030-22102
EA No. 88-147

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

Brigham and Women's Hospital
ATTN: H. Richard Nesson, M.D.
President
75 Francis Street
Boston, Massachusetts 02115

Gentlemen:

Subject: RESPONSE TO NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF
CIVIL PENALTY (Combined Inspection Report Nos. 030-12239/87-001,
030-15070/87-001 and 030-22102/87-001)

This refers to your letter dated August 6, 1988, in response to the Notice of Violation and Proposed Imposition of Civil Penalty sent to you with our letter dated July 6, 1988. Our letter and Notice described violations identified during an NRC inspection completed on April 28, 1988. Members of your staff provided additional explanations of your responses during the meeting held at your request in our office in King of Prussia, Pennsylvania on September 22, 1988. We believe this meeting was useful in helping us better understand your corrective actions and plans for managing your licensed program.

In your response to the Notice, you (1) provide a check for \$5,000 in full payment of the civil penalty; and, (2) deny one of the violations (Item B) in part and two other violations (Items C and E) in total. After careful consideration of your response, we have concluded, for the reasons provided herein, that the three violations denied in your response did, in fact, occur as stated, and that sufficient basis was not provided for retraction of any of the three violations.

We have reviewed the corrective actions set forth in your August 6, 1988 response and, as described in the enclosure to this letter, additional information is required in response to Violations B and E. Please provide the information described in the enclosure within 30 days of the date of this letter to the Regional Administrator, USNRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406. We will review implementation of your corrective action during subsequent inspection.

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 and your response will be placed in the NRC's Public Document Room.

The response directed by this letter is 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.

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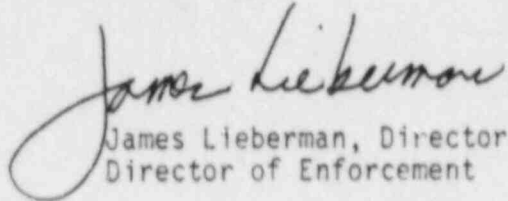
OCT 25 1988

Brigham and Women's Hospital

- 2 -

Thank you for your cooperation in this matter.

Sincerely,


James Lieberman, Director
Director of Enforcement

Enclosures:

1. Evaluation and conclusion
2. Licensee Letter, dated July 1, 1987

cc:

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

Mr. Nicholas J. Johnson
Vice President
Brigham and Women's Hospital
75 Francis Street
Boston, Massachusetts 02115

Enclosure

Evaluation and Conclusion

In a letter dated August 6, 1988, the licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalty issued on July 6, 1988 concerning violations identified during an NRC inspection. In its response the licensee denied violation B in part and Violations C and E in total.

Provided below is a summary for each of the licensee's arguments in support of withdrawal of the violation, and the NRC response to those arguments. Further, the licensee provided a comment to Violation A that is also addressed herein.

1. With respect to Violation B, which involved the failure to make an adequate evaluation of iodine-125 in air in restricted areas, the licensee states that an airborne iodine-125 hazard was not likely to exist in the laboratory where a member of its research staff ingested iodine-125. Nevertheless, even though the presence of iodine in the air was unlikely, this did not excuse the licensee from making the required survey since the possibility existed that it could have been in the air. Moreover, since 10 CFR Part 20 of NRC regulations requires that each licensee relate an individual's intake of radioactive material to an inhaled concentration, regardless of the true route of ingestion, the violation occurred as stated in the Notice.

The licensee further states its intent to develop a thyroid monitoring system, in conjunction with the Harvard University Environmental Health and Safety Office, which will bring the monitoring program into full compliance by July 1, 1989. The licensee did not submit a description of the thyroid monitoring program it intends to use in the interim. Therefore, the licensee must provide such a description, including a discussion of the efficiency and calibration of the counting equipment, the counting geometry, and the iodine-125 biological distribution factors that will be used to relate uptakes to inhaled air concentrations.

2. With respect to Violation C, which involved radiation levels in an unrestricted area of 4.5 millirem per hour, the licensee denies this violation. The licensee cites verbal reports from the Joint Center for Radiation Therapy (JCRT) Health Physicist and a Senior Health Physics Technician that the inspector could not reproduce a 4.5 millirem per hour measurement made earlier that day in a stairwell adjacent to a room housing a brachytherapy patient. As discussed in the inspection report, our inspector originally measured five millirem per hour, but could not reproduce this measurement later. However, he did measure 4.5 millirem per hour in the presence of the JCRT representative. Therefore, the violation occurred as stated in the Notice. Further, the inspector observed the patient on both occasions and did not notice any substantial shift in the patient's position within the room. If patient movement can substantially increase or reduce the effectiveness of the radiation shielding, more frequent surveys of unrestricted areas should be performed. In any case, a survey should evaluate the worst case situation to determine whether the circumstances comply with the regulations.

Despite its denial of this violation, corrective actions that appear adequate to prevent recurrence of this violation were described. No further response to this violation is required.

3. With respect to Violation E, which involved the use of radioisotopes by several individuals without authorization of the Radiation Safety Committee, the licensee denies this violation. The licensee's response states that the Thorn Building, which houses research laboratories administered by Harvard University and Brigham and Women's Hospital (BWH), is owned by Harvard University and the Howard Hughes Medical Institute, and authorization for use of radioactive material on certain floors of the building was appropriately granted by Harvard University, the employer of personnel in those laboratories.

The BWH license authorizes the Thorn Building as a location for the use of radioactive materials. Moreover, as documented in the enclosed correspondence dated July 1, 1987 between Dr. David Drum, Radiation Protection Officer, BWH and Dr. R. Tanis, Harvard Medical School, BWH has full responsibility for radiation safety in the Thorn Building labs. As such, the laboratories, procedures and personnel using licensed material in the Thorn Building must be authorized by the BWH Radiation Safety Committee. Since they were not authorized by the BWH Radiation Safety Committee, the violation occurred as stated in the Notice.

In addition, the NRC could also have cited the violation against License Condition 12A which states that licensed material shall be used by or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, David E. Drum, M.D., Chairman.

The licensee's response fails to confirm that the BWH Radiation Safety Committee (RSC) will review the use of radioactive material in the Human Genetics Department in the Thorn Building or that the BWH and Harvard license's will be appropriately amended. It is our policy that each physical location be an authorized place of use for only one NRC licensee. While we prefer to authorize use in an entire building, we will authorize individual rooms if it can be done clearly. This issue was the subject of extensive discussion during the meeting on September 22, 1988 with the licensee, and possible solutions were discussed. The licensee needs to resolve this issue and to either provide this office confirmation that the BWH RSC will provide the appropriate review or provide a request for a licensee amendment.

4. In addition to the denials, in whole or in part, of the three violations described above, the licensee's response notes, with respect to Violation A, that the strong regulatory response to its detection of an excessive thyroid uptake by an individual might discourage licensees from monitoring employees who use only small amounts of iodine-125.

This violation was based on a worker's uptake of iodine-125 in excess of regulatory limits. While the NRC encourages licensees, particularly those of broad scope, to maintain surveillance programs which are superior to a minimally acceptable program, it cannot overlook excessive personnel exposures which are detected by this more extensive monitoring. The NRC does not believe that responsible licensees will reduce their monitoring programs to reduce the likelihood of identifying safety problems or to avoid regulatory problems. In fact, we expect that responsible licensees will use such findings to target and strengthen weaknesses in their programs.

Enclosure

- 3 -

Therefore, in your response to this letter, please describe your safety philosophy and your plans to ensure that the facility is not only operated in accordance with the license, but that safety concerns, whenever and wherever they might exist, are appropriately evaluated and resolved. This matter was also discussed at length during the meeting on September 22, 1988. Please formalize the positions you described during that meeting.

NRC Conclusion

The violations occurred as stated in the Notice of Violation dated July 6, 1988.



BRIGHAM
AND
WOMEN'S
HOSPITAL

75 Francis Street
Boston, Massachusetts 02115

Phone: 732-6056

July 1, 1987

Robert Tanis, Ph.D.
Department of Genetics
Harvard Medical School
Brigham and Women's Hospital

Dear Dr. Tanis,

Recently published U.S. Nuclear Regulatory Commission statutes (10 CFR 35) have forced us to scrutinize all of the administrative and record keeping aspects of our Radiation Safety Program.

You and I have talked previously about the dual relationship of Dr. Leder's Department of Genetics both Brigham and Women's Hospital and Harvard Medical School. However, as Radiation Protection Officer for Brigham and Women's Hospital, the responsibility for radiation safety in the Thorn building labs is mine not Harvard's. Thus it may help to clarify several administrative points so that our office may adequately discharge our safety responsibilities as we do with all other labs in the Thorn building.

Specifically, I would like to have new personnel requiring exposure film badges apply for their badge through our office. Our secretary will then contact Harvard Environmental Health Services who will initiate the badging process. The new employee will fill out one of the enclosed forms and return it to our office. We now require (as does Harvard) that the new employee have some type of documented training in safe use of radioisotopes prior to getting a badge and working with isotopes. This requirement can be met by documentation of having completed a prior course or by completion of Harvard's quarterly course. In addition, we are offering a short course here at Brigham and Women's Hospital during the months when Harvard does not offer their course (see



A Teaching Affiliate of Harvard Medical School

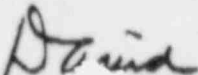
Robert Tanis, Ph.D.
July 1, 1987
Page Two

We have on hand copies of Harvard permits for Drs. Leder, Winston, Cepko, and Seidman. We would like to have copies of Drs. Church and Perrimon's applications as well. It is important for us to know what isotopes are permitted and used under these individual permits. I realize ordering of isotopes is done through Harvard but some are delivered to our Radiopharmacy.

In the near future, I would like to talk with your staff about radiation safety issues, especially as they pertain to Brigham and Women's Hospital. Early in July I'll call you to chat about this.

If there are any questions about the registration of personnel through this office, please call Carol Jankowski, R.N. in the Radiation Safety Office (732-6056). In the meantime, I will ask her to contact your secretary to set up a workable arrangement for registering new employees.

Sincerely yours,


David E. Drum, M.D.
Radiation Protection Officer

DED:JBM

Enclosures

APPLICATION FOR RADIATION BADGE

Brigham and Women's Hospital OR
Harvard Environmental Health Service

Return This Form To:

Radiation Safety Office
c/o David E. Drum, M.D.
Department of Radiology
73 Francis Street
Boston, MA 02115

732-6036

Employee's Card Imprint

Name (PRINT) _____

Male Female

Address _____

Racial ☐ ☐ _____

Date of Birth / /

Date Began Work / /

Work Address at BWH _____

Local Phone No _____

I request that a radiation badge be issued to me. (SELECT ONE)

☐ As a condition of use of radioisotopes I agree to attend the next training session presented by Harvard Environmental Health Services (HEHS) or I enclose with this form evidence of specific radiation safety training courses previously attended. I will ensure that my work habits conform to those in the Radiation Safety Manual issued to my supervising investigator. (Upon return of this form to the Radiation Safety Office, HEHS will be modified and _____

☐ My work will be solely with radiation-producing machines, for which I have received training as listed on a separate paper. (A badge will be issued by the Radiation Safety Office upon receipt of this form.)

Signature of supervising permit holder who is responsible for my safety:

Local/Laboratory Phone No _____

Signed _____

OCT 25 1988

Brigham and Women's Hospital

DISTRIBUTION:

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