

October 17, 1996

John Gergely, M.D., Ph.D.  
Executive Director  
Boston Biomedical Research Institute  
20 Staniford Street  
Boston, MA 02114

SUBJECT: INSPECTION NO. 030-01971/96-001

Dear Dr. Gergely:

This refers to your letter dated June 6, 1996, in response to our letter dated May 7, 1996.

Thank you for informing us of the corrective and preventive actions you documented in response to our correspondence.

During the inspection on March 28, 1996, the inspector took four wipe samples in your restricted areas, one each at the following locations: 1) Dr. Ikemoto's laboratory, 2) the iodination hood in Room 260, 3) the floor outside Cold Room 105A, and 4) the ramp in front of Cold Room 121. These wipes were analyzed in the Region I laboratory. Only wipe 2 showed evidence of activity in excess of background. The results for that wipe were: gross beta,  $1427 \pm 9$  disintegrations per minute (dpm); tritium,  $4530 \pm 40$  dpm; carbon-14,  $1089 \pm$  dpm. Mr. Bondick provided these results to Dr. Wohlrab during a telephone conversation on March 24, 1996 and Dr. Wohlrab explained that he had wipe tested the area in question since the inspection and found it free of contamination.

Your response to item B.2 in our letter states that the Principal Investigator inspects the laboratory after each experiment as indicated in the "Experiment Checklist" (Form 5). According to the copy of your Radiation Safety Manual in our file, Form 5 is your "Radioisotope Receiving Checklist." During the inspection the inspector concluded based on interviews and review of records that the required surveys had not been conducted daily, or after each experiment, were conducted only every three months. You should assure that these surveys are conducted at the required frequency.

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Boston Biomedical Research Institute

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We will review these matters during the next inspection of your licensed activities. Your cooperation with us is appreciated.

Sincerely,

**ORIGINAL SIGNED BY:**

John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety

Docket No. 030-01971  
License No. 20-13748-01

cc:  
Harmut Wohlrab, Ph.D., Radiation Safety Officer  
Commonwealth of Massachusetts

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# BOSTON BIOMEDICAL RESEARCH INSTITUTE

HARTMUT WOHLRAB, Ph.D.,  
RADIATION SAFETY OFFICER

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June 6, 1996

U.S. Nuclear Regulatory Commission  
Washington, DC 20555

ATTN: Document Control Desk

Ref: Reply to a Notice of Violation  
Routine Inspection No. 030-01971/96-001  
License No. 20-13748-01 Docket No. 030-01971

Gentlemen:

Four violations of NRC requirements were identified during the Routine Inspection of March 28, 1996.

- A. A thorough analysis of the list of individuals who have been assigned radiation monitoring badges indicated that the training records of several of them have been missing. Initial indications are however that these individuals have indeed been trained and have attended and passed the *Basic Training Program in Radiation Safety* given by Harvard University Environmental Health and Safety (HUEHS). They are thus authorized to use radioisotopes. Their records must have been misplaced during last year's move of the radiation office and the retirement of the Radiation Safety office secretary. We are taking those individuals with missing records through the reauthorization process.

Individuals, to whom radiation monitoring badges have not been assigned, are not authorized to use radioisotopes. During our semiannual internal inspection of laboratories of licensed Principal Investigators, we will interview these individuals as to their role in experiments that utilize radioisotopes.

Our last annual refresher training lecture for authorized individuals was given on June 7, 1995. Our attendance records indicate that seven authorized individuals did not attend. Our next refresher training lecture will be held in September, 1996, and will have a separate second and obligatory refresher training session to insure attendance *by all authorized individuals*. We always have a separate, voluntary refresher training session for not authorized individuals.

Training records will be complete by July 1, 1996. Our semiannual inspections are being modified, as already discussed, to include not authorized individuals. This will happen after our quarterly Radiation Safety Committee meeting on June 11, 1996. Attendance at the annual refresher training session will be strictly enforced starting with the September, 1996, sessions.


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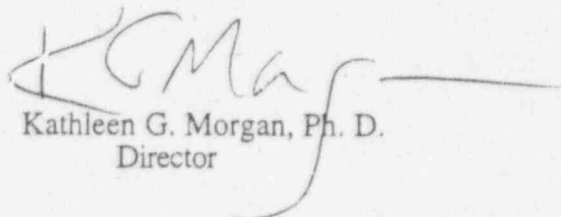
June 6, 1996

- B.1. We are changing our internal inspection procedure. Members of the Radiation Safety Committee will be told of the isotope(s) recently purchased by the Principal Investigator's laboratory to be inspected. The inspection will then concentrate on all the records associated especially with these isotopes. Laboratories with incomplete records will be inspected again within 2 weeks.
- B.2. Laboratories using radioisotopes are inspected routinely at three levels. The Principal Investigator or authorized user inspects his/her laboratory after each experiment as indicated in the Experiment Checklist (Form 5). HUEHS monitors every lab every month for isotopes with monitors and wipes. Members of the Radiation Safety Committee inspect the labs about every six months for record keeping, general good housekeeping practices, as well as isotope contamination. It is thus not clear why the inspectors concluded that "the laboratory of one principal investigator was only checked every three months during the time period since the last inspection, even though work with licensed material was performed on a regular basis."
- B.3. Several instruments as indicated in your letter, have not been calibrated in 1995 due to some confusion in transferring record keeping from a retiring secretary to a new one. During the day of inspection, the secretary insists that PI's bring their monitors to the inspection station. This process was not carried out effectively last year but will be effectively enforced during this year's inspection. All meters will have been recalibrated by July 1, 1996.

Sincerely yours,



Hartmut Wohlrab, Ph. D.  
Radiation Safety Officer



Kathleen G. Morgan, Ph. D.  
Director