

MAY 19 1994

Docket Nos. 030-04605
030-06945

License Nos. 20-01489-01
20-01489-05

Biodevelopment Laboratories, Inc.
ATTN: Joseph Guarnieri
President
30 Memorial Drive
Cambridge, MA 02140-2390

Dear Mr. Guarnieri:

SUBJECT: ROUTINE INSPECTION NOS. 030-04605/94-001 AND 030-06945/94-001

On April 28 and 29, 1994, Sheri A. Arredondo of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Denise Hayes, Director of Compliance and Joseph Swiniarski, Radiation Safety Officer at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

Item 3.B. in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in a Notice of Violation enclosed with our letter dated November 8, 1991. From this inspection, it appears that your corrective actions were not effective since this item has recurred. 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.

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RETURN ORIGINAL TO
REGION I

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Please use the enclosed self-addressed green envelope when you submit your copy to the Regional Administrator, Region I. This will assist us in the timely processing of your response. In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of 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 is appreciated.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Research and Development Section
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix A, Notice of Violation

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

bcc:
Region I Docket Room (w/concurrences)
D. J. Holody, RI

DRSS:RI
Arredondo/cmm
SA
5/16/94

DRSS:RI
Shanbaky
MS
5/19/94