

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
811 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

MAY 13 1981



License No. 43-14991-01

Becton Dickinson Immunodiagnostics
Automated Immunochemistry Systems
ATTN: Dr. LaVell R. Johnson, Vice President
P. O. Box 15350
180 West 2950 South
Salt Lake City, UT 84115

Gentlemen:

This refers to the routine safety inspection conducted by Mr. C. L. Cain of this office on March 25-26, 1981, of the activities authorized by NRC Byproduct Material License No. 43-14991-01 and to the discussion of our findings held by Mr. Cain with members of your staff at the conclusion of the inspection. This also refers to the Enforcement Conference held at our office on April 28, 1981. The subjects discussed in this Conference are described in Appendix B to this letter. The attendees are listed in Appendix C.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements and observations by the inspector.

During this inspection certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing in accordance with the provisions of Section 2.201 of the NRC "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation, enclosed herewith as Appendix A.

In addition, we are concerned about the implementation of your program for management control of your licensed activities that permitted these violations to occur. Consequently, in your reply you should describe, in particular, those

1E07
5/11

8105270 483

actions taken or planned to improve the effectiveness of your management control of the requirements of your license. The last paragraph of your letter should include a statement equivalent to the following:

"I certify that all information contained in this letter, including any supplements attached thereto, is true and correct to the best of my knowledge and belief."

_____ Date

_____ Signature

_____ Title

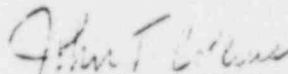
This signature should be notarized.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosed inspection report will be placed in the NRC's Public Document Room. If this report contains any information that you believe to be exempt from disclosure under 10 CFR 9.5(a)(4), it is necessary that you: (a) notify this office by telephone within 10 days from the date of this letter of your intention to file a request for withholding; and (b) submit within 25 days from the date of this letter a written application to this office to withhold such information. If your receipt of this letter has been delayed such that less than seven days are available for your review, please notify this office promptly so that a new due date may be established. Consistent with Section 2.790(b)(1), any such application must be accompanied by an affidavit executed by the owner of the information which identifies the document or part sought to be withheld, and which contains a full statement of the reasons on the basis which it is claimed that the information should be withheld from public disclosure. This section further requires the statement to address with specificity the considerations listed in 10 CFR 2.790(b)(4). The information sought to be withheld shall be incorporated as far as possible into a separate part of the affidavit. If we do not hear from you in this regard within the specified periods noted above, the report will be placed in the Public Document Room.

Becton Dickinson Immunodiagnostics -3-

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,


John T. Collins
Deputy Director

Enclosures:

1. Appendix A, Notice of Violation
2. Appendix B, Summary of Enforcement Conference
3. Appendix C, Attendance List for Enforcement Conference
4. IE Inspection Report 81-01